IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED HEALTHCARE SERVICES, INC., Plaintiff, vs. JAZZ PHARMACEUTICALS PLC, JAZZ PHARMACEUTICALS, INC., JAZZ PHARMACEUTICALS IRELAND LIMITED, HIKMA PHARMACEUTICALS PLC, ROXANE LABORATORIES, INC., HIKMA PHARMACEUTICALS USA INC., EUROHEALTH (USA), INC., AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC., LUPIN LTD., AND LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. **COMPLAINT** JURY TRIAL DEMANDED

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I. INTRODUCTION

1. This is a case about efforts by a branded drug manufacturer and several generic manufacturers to unlawfully abuse the patent laws for profit by monopolizing the market for a drug that was invented nearly 150 years ago. The drug is sodium oxybate, sold under the brand name Xyrem, also known as γ-Hydroxybutyric acid (GHB). It is a naturally occurring substance found in the central nervous system. It was first reportedly synthesized in 1874, which makes it 20 years older than aspirin. The branded drug manufacturer is Jazz Pharmaceuticals, Inc., for which Xyrem has represented the majority of its revenues over the past 15 years.

2. Beginning in the 1960s, sodium oxybate attracted attention for its potential medicinal uses, including for the treatment of narcolepsy. Narcolepsy is a disorder characterized by excessive daytime sleepiness ("EDS") and intermittent manifestations of REM sleep during wakefulness. In 1994, the Food and Drug Administration's ("FDA") Orphan Products Development Division and a non-profit advocacy organization approached a small Minnesota-based drug company, Orphan Medical, to suggest the development of sodium oxybate for treatment of cataplexy, which is a common symptom of narcolepsy manifested by sudden episodes of bilateral skeletal muscle weakness induced by an emotional trigger such as laughter, anger, embarrassment, or surprise. This suggestion was based on promising results obtained by several independent investigators who reported the efficacy of sodium oxybate as a treatment of narcolepsy. Orphan Medical agreed and, in 2002, obtained FDA approval to market sodium oxybate for the treatment of cataplexy associated with narcolepsy in adults. Orphan branded its

product Xyrem. In 2005, Orphan Medical obtained FDA approval to market Xyrem for EDS associated with narcolepsy in adults. Until 2021, Xyrem was the only drug approved by the FDA to treat both EDS and cataplexy associated with narcolepsy. In 2020, the FDA also approved Jazz's follow-on sodium oxybate product, Xywav, for the treatment of those conditions.

3. In 2005, Jazz Pharmaceuticals, Inc.[1] engineered a leveraged acquisition of Orphan. At first, the acquisition was not profitable. In 2009, while on the verge of bankruptcy, Jazz replaced its management team. Jazz thereafter embarked on a multifaceted scheme to dramatically increase the price of Xyrem. In 2014, Bloomberg ranked Xyrem first overall in an analysis of drug price increases—increases that have continued unabated. Xyrem has been Jazz's cash cow, typically providing up to 75% (and at times more) of Jazz's revenues, with profit margins often above 90%. Jazz reported annual Xyrem sales of more than $1.6 billion in 2019.

4. Jazz could maintain these extreme prices and sales volumes only by squelching generic competition. As Jazz's CEO bragged at a 2011 investor conference, "There's really no competition" for Xyrem.[2] Although the patent laws are designed to promote innovation by creating rights of "exclusivity" for inventors of new products,

[1] Unless otherwise noted, this Complaint uses the term "Jazz" to refer to Defendants Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals Ireland Limited, and Jazz Pharmaceuticals Public Limited Company.

[2] *Conference Call Transcript; Jazz Pharmaceuticals, Inc. at Piper Jaffray Health Care Conference*, Jazz Pharmaceuticals (Nov. 30. 2011), https://investor.jazzpharma.com/node/12191/html.

Jazz's primary innovations have been unlawful ways to artificially extend its Xyrem monopoly. Jazz's exclusionary tactics have included:

a. Abusing a risk-management procedure known as a Risk Evaluation and Mitigation Strategy (REMS) to prevent generic entry;

b. Obtaining various invalid patents and filing *seriatim* sham lawsuits against generic manufacturers intended to drag out litigation over the rights of generic manufacturers to launch their own products;

c. Filing sham citizen's petitions in 2012 to deter generic entry; and

d. Entering into "reverse-payment" agreements in which Jazz agreed to pay generic competitors a share of its Xyrem monopoly profits in exchange for the generics' agreements not to compete against Xyrem for a period of years.

5. As a result of Jazz's unlawful conduct, Jazz will maintain its sodium oxybate monopoly through at least 2023. Purchasers, including healthcare payors, such as Plaintiff United HealthCare Services, Inc. ("UHS"), have paid grossly inflated prices for Xyrem, and will continue to pay grossly inflated prices for sodium oxybate products so long as the anticompetitive agreements remain in effect. UHS seeks damages for the overcharges it paid as a result of Defendants' conduct as well as injunctive relief to prevent the Defendants from continuing their unlawful agreements.

II. PARTIES

6. UHS is a corporation organized and existing under the laws of Minnesota with its principal place of business in Hennepin County, Minnesota. It is a wholly owned

subsidiary of UnitedHealth Group, Inc. ("UHG"), which is headquartered in Minnetonka, Minnesota.

7. UHS engages in servicing prescription drug managed care programs provided to members and beneficiaries under insurance plans offered by UHS's subsidiaries and affiliates, which, together, constitute the largest single health insurance carrier and services provider in the United States, and serve some 70 million individual insureds ("UnitedHealthcare Insureds").[3] UHS is the centralized and primary contracting entity responsible for payments made for pharmaceutical drugs dispensed to UnitedHealthcare Insureds throughout the country. From its headquarters in Hennepin County, Minnesota, UHS negotiates and executes contracts with Pharmacy Benefit Managers ("PBMs") on behalf of itself and its health plan subsidiaries and affiliates ("UnitedHealthcare Plans"), and during the relevant time period, was (and is) contractually responsible for the payments made under those contracts, including for Xyrem dispensed to UnitedHealthcare Insureds during the relevant time period.

8. UHS is the parent company of, or otherwise an affiliate/related company to, each of the UnitedHealthcare Plans, which issue health insurance to UnitedHealthcare Insureds, including for coverage of prescription drug costs. The UnitedHealthcare Plans issue insurance to UnitedHealthcare Insureds covering prescription drugs in the form of (1) fully insured commercial ("Commercial") plans; (2) Medicare plans; and (3)

[3] For purposes of this Complaint, the term UnitedHealthcare Insureds does not include members of self-insured or self-funded health plans, also known as self-funded or Administrative Services Only ("ASO") customers.

Medicaid plans. The UnitedHealthcare Plans provide these prescription drug insurance benefits to UnitedHealthcare Insureds in all 50 states, the District of Columbia, and Puerto Rico. These UnitedHealthcare Plans are listed in the attached Exhibit A.

9. UHS seeks recovery for all unlawful overcharges it incurred for reimbursements of sodium oxybate dispensed to UnitedHealthcare Insureds, including all those receiving insurance or health benefits from any of the UnitedHealthcare Plans (or their predecessors or successors). Xyrem was and is exclusively dispensed by Express Scripts Specialty Distribution Services, Inc. ("ESSDS"), the only pharmacy authorized under the REMS program to distribute Xyrem.

10. UHS is the proper entity to pursue all forms of relief, including damages, for injury and losses incurred as alleged in this Complaint. Nonetheless, out of an abundance of caution, and to assure the Court that there is no potential for any duplicative indirect purchaser/payor recovery, UHS has obtained assignments from the UnitedHealthcare Plans, conveying to UHS any claims and rights to recoveries they may have in connection with the matters alleged in this Complaint. UHS asserts those assigned indirect purchaser/payor claims in the alternative to the claims of UHS, to the extent that such assignors are found to be sole owners of any claims that are non-duplicative to those of UHS. Accordingly, to the extent that the Court were to find such assignments are required for any claims, all subsequent references to UHS include itself and assignors UnitedHealthcare Plans, unless expressly indicated otherwise.

11. Defendant Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in

Dublin, Ireland. Its U.S. headquarters is located in Palo Alto, California. Jazz Pharmaceuticals, Inc. principally develops, manufactures, and markets brand name drugs. During the relevant time period, Jazz Pharmaceuticals, Inc. employed, and solicited employees for, sales positions in Minnesota.

12. Defendant Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, with its principal place of business in Dublin, Ireland.

13. Defendant Jazz Pharmaceuticals Public Limited Company is an Ireland public limited biopharmaceutical company organized and existing under the laws of Ireland, with its principal place of business in Dublin, Ireland. Jazz Pharmaceuticals plc common stock is publicly traded in the United States on the NASDAQ stock exchange. Jazz Pharmaceuticals plc is the parent company of Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited.

14. Among other things, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited were parties to agreements with generic manufacturers and were directly involved in the negotiation of the unlawful agreements described in this Complaint. Each of the three Jazz defendants was directly and substantially involved in planning and undertaking the anticompetitive acts alleged in this complaint. This Complaint refers to the Jazz entities, collectively, as "Jazz."

15. Defendant Hikma Pharmaceuticals plc is a public limited company organized and existing under the laws of the United Kingdom, with its principal place of business in London and its U.S. headquarters in Eatontown, New Jersey.

16. Defendant Hikma Pharmaceuticals USA Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in Eatontown, NJ. It is a wholly owned subsidiary of Hikma Pharmaceuticals plc. Before June 20, 2018, Hikma Pharmaceuticals USA Inc. was organized under the name West-Ward Pharmaceuticals Corp., which had been acquired by Hikma Pharmaceuticals plc in 1998.

17. Defendant Roxane Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business in Columbus, Ohio. West-Ward Pharmaceuticals Corp. purchased Roxane Laboratories, Inc. in 2016. Roxane Laboratories, Inc. is a wholly owned subsidiary of Hikma Pharmaceuticals plc.

18. Defendant Eurohealth (USA), Inc. is a holding company for Hikma Pharmaceuticals USA Inc. and a wholly owned subsidiary of Hikma Pharmaceuticals plc, organized and existing under the laws of the State of Delaware, with its principal place of business at 246 Industrial Way West, Eatontown, NJ, 07724. This Complaint collectively refers to the Hikma entities as "Hikma."

19. Among other things, Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Eurohealth (USA), Inc., and Hikma Pharmaceuticals plc were parties to the document styled as the "Settlement Agreement" in this complaint. Each of the Hikma-related defendants was directly and substantially involved in planning, entering into, and performing under the agreements reached beginning in 2017, as alleged in this Complaint.

20. Defendant Amneal Pharmaceuticals, LLC ("Amneal LLC") is a Delaware limited liability company with its principal place of business in Bridgewater, New Jersey.

21. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of New York, with its principal place of business at One Ram Ridge Rd., Chestnut Ridge, New York. It is a subsidiary of Endo International plc, an Irish company with its U.S. headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed an acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par Pharmaceutical, Inc., and combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. As used in this Complaint, "Par" encompasses relevant predecessors and successors-in-interest.

22. Defendant Lupin Ltd. is a public limited company organized and existing under the laws of India, with its principal place of business in Mumbai, India.

23. Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Baltimore, Maryland. It is a wholly owned subsidiary of Lupin Ltd. Lupin has a registered agent for service of process in Minnesota. This Complaint collectively refers to the Lupin entities as "Lupin."

24. All of Defendants' actions described in this Complaint were authorized, ordered, and/or undertaken by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with Defendants' actual and/or apparent authority.

III. JURISDICTION AND VENUE

25. This action seeks relief under federal and state antitrust and consumer protection laws to recover civil damages and costs of suit, including reasonable attorneys' fees, against Defendants for the injuries sustained by UHS and also for equitable relief in the form of an injunction rescinding the unlawful agreements described below, restitution and/or disgorgement of Defendants' unjust enrichment.

26. The Court has subject-matter jurisdiction over this matter pursuant to 15 U.S.C. § 26 and 28 U.S.C. §§ 1331, 1332, and 1337.

27. The Court has subject-matter jurisdiction over the state-law claims alleged in this action pursuant to 28 U.S.C. § 1367, as the state law claims are so related to the federal claims as to form part of the same case or controversy. Such supplemental or pendent subject-matter jurisdiction will also avoid unnecessary duplicity or multiplicity of actions, and should be exercised in the interest of judicial economy, convenience, and fairness. The court would also separately have jurisdiction over these claims pursuant to 28 U.S.C. § 1332(a), as the amount in controversy exceeds $75,000 and involves diversity of citizenship.

28. Venue is proper in this District pursuant to 28 U.S.C. § 1391. At all relevant times, each Defendant resided, transacted business, and/or was found or had agents in the United States, including this District. Each Defendant employs, and at all relevant times has employed, sales and other personnel in this District for the purpose of marketing, selling, and distributing pharmaceuticals, including the subject drugs, in Minnesota.

29. During the relevant time period, Defendants marketed, sold, and/or shipped pharmaceutical drugs (including those at issue) in a continuous and uninterrupted flow of interstate commerce in the United States, including into this District. Defendants' conduct alleged in this Complaint had a direct, substantial, and reasonably foreseeable effect on trade and commerce in this District. Defendants' anticompetitive conduct was directed at and had the intended effect of causing injury to persons (including UHS) residing in, located in, or doing business throughout the United States—including in this District.

30. Each Defendant is subject to the personal jurisdiction of this Court for one or more of the reasons stated below:

a. Defendants are subject to service of process for this action as provided in 15 U.S.C. § 22;

b. Each Defendant is amenable to service of process because, as alleged in this Complaint, it inhabits, transacts business in, has continuous or systematic contacts with, and/or is found or has sufficient minimum contacts in the United States sufficient to satisfy due process. While Defendants are headquartered outside this District, they nevertheless engaged in the business of developing, distributing, advertising, and/or selling drug products into this District specifically and purposefully;

c. Each Defendant is amenable to service of process pursuant to Rule 4(k)(1)(A) of the Federal Rules of Civil Procedure and the long-arm

statute of the State in which this Federal Court sits because, *inter alia*, and as alleged in this Complaint, each Defendant has transacted business in this District and/or has contracted to supply services or things in this District, and because the District's long-arm statute extends jurisdiction to the limits of due process and Defendant has sufficient minimum contacts with the District to satisfy due process; and/or;

d. Based on the allegations in this Complaint, each Defendant is subject to the general and specific personal jurisdiction of this Court because it has purposefully directed its contacts and conduct at the forum District and has purposefully availed itself of the laws of this District. As alleged in this Complaint, Defendants engaged in anticompetitive conduct that was intended to have, and did have, direct, substantial, and reasonably foreseeable effects on the commerce in this District.

IV. REGULATORY BACKGROUND

A. Third Party Payors in the Prescription Drug Marketplace

31. UHS pays for numerous prescription drugs, including Xyrem, in satisfaction of the needs of UnitedHealthcare Insureds.

32. The prescription drug marketplace has unique characteristics that distinguish it from other markets. First, access to prescription drugs is highly regulated. Second, although it is the patient who ultimately ingests the prescription drug, access to

the drug is controlled by a physician who must provide a patient with a prescription for the drug and by the pharmacist who fills the prescription. Third, for the majority of Americans (i.e., those with insurance coverage) payment for prescription drug costs (after member cost-sharing) is handled by third-party payor insurers.

33. Third-party payors, including UHS, depend on the existence of real competition within the regulatory structure that governs pharmaceutical manufacturers, including from generics.

B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

34. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

35. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer must list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within thirty days of their issuance. 21 U.S.C. §§ 355(b)(l) & (c)(2).

36. The FDA relies completely on the brand manufacturer's representations about patent validity and applicability, as it does not have the resources or authority to verify the validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

C. The Hatch-Waxman Act

37. In 1984, Congress amended the FDCA through enactment of the Drug Price Competition and Patent Restoration Act, commonly known as the Hatch-Waxman Act. Congress's principal intent was for Hatch-Waxman to simplify and reduce regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process through the filing of an Abbreviated New Drug Application ("ANDA"), to introduce competition into the marketplace.

38. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent[4] to the brand drug. The FDA assigns oral-dosage-form generic drugs that are pharmaceutically equivalent and bioequivalent to their brand-name counterpart an "AB" rating.

[4] Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

39. Congress enacted the Hatch-Waxman Act to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

40. The Hatch-Waxman Act achieved both goals, advancing substantially the rate of generic product launches.

D. Paragraph IV Certifications

41. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

42. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent

infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay. Settlement between the branded and generic can also lead to entry before expiration of the 30-month stay.

43. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic (other than, potentially, an "authorized generic" sold by the brand manufacturer as discussed below) for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period.

44. To generic manufacturers, entering the market first with the 180-day exclusivity period is an important objective. Before generic entry, the brand drug is typically priced well above marginal cost ("supracompetitive levels"). During the 180-

day period of exclusivity, the generic price, while lower than the branded price, is still much higher than it would be in the presence of two or more generic competitors. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases up to 80%, 90%, or more, when there are multiple generic competitors on the market. For a generic manufacturer, being able to sell at the higher duopoly price for 180 days may be worth hundreds of millions of dollars.

45. Under this regulatory scheme, NDA-holders have strong financial incentives to "game the system" by listing patents in the Orange Book, even if such patents are not eligible for listing because they are invalid or unenforceable, and by suing any generic competitor that files an ANDA with a Paragraph IV certification, even if the generic competitor's product does not actually infringe the listed patent because merely filing suit delays generic entry during the automatic 30-month stay. Although such gamesmanship is unlawful, the profits to NDA-holders are often far greater than the sanctions they would reasonably expect to pay if challenged.

46. Similarly, the first generic applicant can help the brand manufacturer "game the system" by agreeing to delay its own market entry, which effectively blocks the market entry of all generic manufacturers because later generic applicants cannot launch until the first generic applicant uses or forfeits its 180-day exclusivity period.

E. Benefits of Generic Drugs

47. Generic versions of brand name drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their brand name

counterparts. ANDAs for orally available solid dosage forms (tablets, capsules, etc.) that meet all of the requirements for FDA approval are assigned an "AB" rating by the agency. AB-rated generics are deemed by the FDA to be therapeutically equivalent and pharmaceutically equivalent to their brand-name counterparts.

48. An AB rating for a generic drug is significant. All states permit (and some states require) pharmacists to substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing physician (unless the prescription states "Dispense as Written").

49. Many third-party payors, such as UHS, whose members account for a substantial share of purchases in the market, have adopted policies to encourage the substitution of lower-cost AB-rated generic drugs for their branded counterparts.

50. Until a generic manufacturer enters the market with an AB-rated generic product, there is no bioequivalent generic drug which competes with the brand-name drug and the brand name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

51. The launch of a generic drug creates price competition that provides cost savings for all purchasers of the drugs. When an AB-rated generic enters the market, it quickly captures sales of the corresponding branded drug, often capturing 80% or more of the market within the first six months. The Federal Trade Commission ("FTC") has estimated that, within a year of the first generic entrant, the generic version on average takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. Prices for the generic drugs typically decline further as more generic companies

compete with one another. As a result, brand name companies, such as Jazz, view competition from generic drugs as a grave threat to their profits.

F. Risk Evaluation and Mitigation Strategies Programs

52. Since at least the 1960s, the FDA has examined and implemented various methods for managing risks related to pharmaceutical products. Methods have included disclosure and labeling requirements. The Controlled Substance Act of 1970 saw the regulation of manufacturers, prescribers, dispensers, and labels and permitted the FDA to require warnings on packages. 21 U.S.C. § 801 *et seq.* (2002).

53. In the 1990s, the FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. Then, in the 2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), in which manufacturers voluntarily instituted risk minimizing plans.

54. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the REMS to be implemented with respect to certain pharmaceutical products "that have already been approved" and directs the Secretary of Health and Human Services ("HHS") to establish an active post-market drug surveillance infrastructure. 21 U.S.C. § 355-1(f)(8). Drug companies with approved RiskMAP programs were "deemed" compliant but required to obtain FDA approval under FDAAA (the term "deemed REMS" means a RiskMAP program pending approval as a REMS).

55. For example, in March of 2008, the FDA deemed the Xyrem RiskMAP to be a REMS program; however, Jazz was required to formally submit to the FDA a proposed REMS for review within 180 days of that notice. In September 2008, Jazz

submitted its existing RiskMAP as the REMS for Xyrem and asked the FDA to approve it under the FDAAA. In that plan, Jazz led the FDA to believe that the single-pharmacy distribution protocol was the best way to effectuate the overall restrictions on distribution necessary for safe use of the drug.

56. A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

57. Since the statute's enactment in 2007, REMS have been increasingly common in the FDA approval process. In 2016, for example, roughly 40% of new drugs had REMS programs (although REMS applied to only about six percent of all FDA approved brand name drugs, as REMs may be removed if they become unnecessary).[5] In addition, Elements to Assure Safe Use ("ETASU") requirements, which are required medical interventions or other actions by healthcare professionals prior to prescribing or dispensing the drug, have become increasingly common.

58. FDA Commissioner Scott Gottlieb, M.D. recently noted that "some companies also try to game the system and use REMS to delay the entry of generics."[6] In situations where a generic drug applicant wants to market a generic version of a drug that has a REMS with ETASU, the brand and generic drug makers are required to develop a

[5] Brittany LaCouture, *REMS and Brand-Generic Negotiations* (Oct. 20, 2016), available at https://tinyurl.com/y4ewuows.

[6] U.S. Food and Drug Administration, *FDA In Brief: FDA affirms its commitment to efficient adoption of Risk Evaluation and Mitigation Strategy plans and to making sure they do not impede generic drug development* (Apr. 4, 2019), available at https://tinyurl.com/y4je3kau.

single, shared REMS program unless the FDA waives that requirement and permits the generic drug to use a different, comparable aspect of the ETASU.

59. REMS are intended to give the FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with particular pharmaceutical products. The statute explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. 28 USC §305-1(f)(8).

60. Notwithstanding the regulatory scheme's prohibition on misuse of REMS to block or delay generic competition, brand manufacturers sometimes seek to unlawfully perpetuate their monopoly by abusing and "gaming" REMS programs. Some estimates on the cost of REMS abuse are as high as $5.2 billion on the federal government, and $5.8 billion on private market participants like UHS.[7]

G. The Impact of Authorized Generics

61. The 180-day marketing exclusivity for first filers does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period, pursuant to its own approved NDA. Such an "authorized generic" is identical to the brand drug, but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition created by an authorized generic during the 180-day exclusivity period leads to lower prices for generic drugs and a decrease in brand name sales.

[7] Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers* (Sept. 2018), https://tinyurl.com/y272qvlb.

62. In its study *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*[8], the FTC found that authorized generics capture a significant portion of sales, reducing the revenues generated by the first-filer's generic product by 40-52% during the 180-day exclusivity period. The first-filing generic makes significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first filer; and (2) the presence of an additional generic in the market leads to lower overall generic prices. This competition benefits drug purchasers. Conversely, the lack of such competition harms purchasers by reducing choice and increasing prices.

63. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, during the relevant time period, brand manufacturers often raised the brand-name price to extract higher profits from the small number of "brand-loyal" patients.

H. The Economics of Reverse-Payment Agreements

64. Reverse-payment agreements arise in response to the threatened loss of exclusivity from patent challenges by generic drug makers. Reverse-payment agreements

[8] Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (Aug. 2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

interrupt the established process by which generic drug competition reduces drug prices. In a reverse-payment agreement, the brand pays the generic (the alleged patent infringer) to dismiss its patent challenge and forego generic entry for a period of time.

65. From an economic perspective, there is reason to scrutinize any reverse-payment agreement because it arises in a unique context. In Hatch-Waxman litigation, the generic firm does not claim damages from the brand company that owns the patent. Thus, a typical reason for a settlement payment—to compensate for damages that have allegedly accrued—does not exist. Thus, the very existence of the payment is an unusual feature of the agreement that requires explanation and invites careful scrutiny.

66. Absent the deterrence effect of antitrust law, reverse-payment agreements would be economically rational for both the branded drug maker and the generic manufacturer. By delaying generic entry, the branded manufacturer preserves a stream of supracompetitive profits. The branded manufacturer can use those profits to pay the generic manufacturer more than the generic manufacturer would have earned had it entered the market and competed against the branded manufacturer's product and any subsequent generic entrants. Although both drug companies profit from that arrangement, they do so at the expense of drug purchasers who pay supracompetitive prices and are deprived of the benefits of competition, including the opportunity to purchase lower-priced generics. As the prohibition on reverse-payment agreements has become more institutionalized, brand manufacturers have sought to mask their "settlement" agreements with generic manufacturers to create the false appearance of a pro-competitive settlement agreement.

67. Reverse-payment agreements that include an agreement by the branded manufacturer not to launch an authorized generic ("no-AG" provision) are even more harmful to competition than reverse-payment agreements involving only a cash transfer because, unlike cash payments, no-AG provisions delay generic entry and continue to restrict competition even after generic entry by eliminating competition between the generic manufacturer's product and the authorized generic. The profits used by the branded manufacturer to compensate the generic manufacturer in a no-AG provision come from the pockets of purchasers (including UHS) who would otherwise pay the drug companies less in the absence of the no-AG agreement.

V. DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. The History of Sodium Oxybate

68. Synthesis of the chemical sodium oxybate[9] was first reported in 1874. Beginning in the 1960s, sodium oxybate, under the name GHB,[10] was marketed in the United States as an unregulated dietary supplement in health food stores, training gyms, fitness centers, and on the Internet beginning in the 1980s.[11] It was also the subject of

[9] GHB is the International Union of Pure and Applied Chemistry chemical name for the sodium salt of γ-hydroxybutyric acid, whereas sodium oxybate is the international drug name for the identical compound. This complaint uses the terms interchangeably.

[10] Gamma-hydroxybutyric acid (GHB) Critical Review Report, World Health Organization Expert Committee on Drug Dependence Thirty-fifth Meeting, Hammamet, Tunisia, 4-8 June 2012.

[11] David E. Fuller, M.D., and Carl S. Hornfeldt, Ph.D., *From Club Drug to Orphan Drug; Sodium Oxybate (Xyrem) for the Treatment of Cataplexy*, Pharmacotherapy 2003; 23(9): 1205–1209.

numerous preclinical and clinical studies for treatment of various diseases and conditions, including treatment of insomnia.

69. By 1990, GHB had gained notoriety as a substance of abuse. Users reported effects of disinhibition similar to that associated with alcohol consumption but without "hangover" effects. At the same time, an increasing number of people taking GHB experienced overdoses requiring hospital emergency care; many had combined GHB with alcohol, which produces synergistic CNS depressant effects. GHB was also implicated in an increasing number of drug-facilitated sexual assaults. Like many other CNS depressants, GHB can cause anterograde amnesia, especially when combined with alcohol, leaving the assault victim unable to recall details of the event.

70. In 1990, the FDA warned against, and then banned, consumption of GHB after several reports of overdose. Despite the ban on sales, GHB continued to be abused, which eventually resulted in the DEA designating it as a Schedule I controlled substance under the Controlled Substances Act. This designation threatened to hinder future development of GHB for therapeutic applications. Successful lobbying efforts on behalf of physicians and patients, however, led to modification of the Controlled Substance Act to create a bifurcated schedule for GHB, allowing sodium oxybate to be designated a Schedule III controlled substance for medical purposes while retaining Schedule I penalties for illegal use.

B. The Development of Sodium Oxybate As a Treatment for Narcolepsy

71. In 1994, the National Organization of Rare Disorders and the FDA Orphan Products Development Division approached Orphan Medical, Inc., a Minnetonka,

Minnesota-based company to suggest the development of sodium oxybate for treatment of cataplexy.[12] This suggestion was based on promising results obtained by several independent investigators who reported the efficacy of sodium oxybate as a treatment for narcolepsy. These results were supported by studies that dated back to the 1970s.

72. Narcolepsy is a sleep disorder classically described as consisting of a group of four symptoms: EDS, cataplexy, sleep paralysis, and hypnagogic hallucinations believed to represent the outward manifestations of a disrupted sleep-wake cycle. Cataplexy is the second most common symptom of narcolepsy. Because there is no cure for narcolepsy, patients rely on pharmacological agents to enable them to lead the fullest personal and professional lives possible.

73. Orphan eventually submitted a new drug application to the FDA. On July 17, 2002, the FDA approved sodium oxybate for the treatment of cataplexy in patients with narcolepsy. The approval provided New Chemical Entity ("NCE") exclusivity through July 17, 2007. The FDA extended the exclusivity period to July 17, 2009 when it designated Xyrem an orphan drug because it treated a rare disease.

74. Orphan Medical branded the product Xyrem. Xyrem is an oral solution that is recommended to be taken two times each night, the first dose right at bedtime and the second dose two-and-a-half to four hours later.

75. Because of concerns about the risk of drug diversion, Orphan Medical collaborated with the FDA, experts in drug abuse prevention, and clinicians to create the

[12] David E. Fuller, M.D., and Carl S. Hornfeldt, Ph.D, *supra* n. 11.

Xyrem Risk Management Program, known as "RiskMAP." The program's goals were to ensure responsible distribution of Xyrem to patients with narcolepsy and to provide education to physicians and patients about safe and responsible administration of the drug. Components of the original plan included (a) a single, centralized pharmacy housed in a secure facility, (b) a program to educate physicians and patients about the risks and benefits of Xyrem, (c) requiring prescribers and patients to read educational materials before filling the initial prescription, and (d) maintenance of a registry of all patients and a record of all prescribers. The centralized pharmacy maintained comprehensive patient and physician registries and verified the eligibility of prescribing physicians before filling Xyrem prescriptions. In addition, pharmacists were trained to be alert for compliance issues and suspicious behavior. Under the RiskMap program, Orphan owned the inventory and the centralized pharmacy maintained it on consignment.

76. From the date of its FDA approval, Jazz has dispensed Xyrem directly to patients under the RiskMAP and REMS through ESSDS.

C. Jazz Acquires Orphan Medical and All Rights to Xyrem

77. In April 2005, Jazz Pharmaceuticals, then a small privately held drug company formed in 2003, announced plans to acquire Orphan Medical (and thereby all rights to Xyrem) in a leveraged acquisition.[13] Xyrem has since been Jazz's main source of revenue, contributing up to 75% (or more) of Jazz's revenue.

[13] Businesswire, *Jazz Pharmaceuticals to Acquire Orphan Medical; Combines Orphan Medical's Growing Central Nervous System Product and Commercial Team with Jazz Pharmaceuticals' Development Pipeline* (Apr. 19, 2005), available at https://tinyurl.com/y3ev85of.

78. In October 2005, the FDA approved Xyrem for the treatment of EDS in adult patients with narcolepsy. EDS is the most common and disabling symptom of narcolepsy. It is present in all patients with the disease.

79. Subsequent to approval, the FDA granted Xyrem an NCE exclusivity of five years from the NDA approval date, expiring on July 17, 2007, and orphan drug exclusivity of seven years from the NDA approval date, expiring on July 17, 2009. These exclusivity grants meant that Xyrem would not face competition from generic competitors until at least mid-2009.

D. The Xyrem Patents

80. After acquiring Orphan Medical, Jazz filed for and obtained several patents claiming aspects of Xyrem and its use. These patents were obtained through a practice sometimes called "evergreening," in which the patentholder seeks additional patents on different aspects of a drug—different forms of release, different methods of use, different dosages, and different combinations or variations—in order to artificially extend the life of a patent or other exclusivity. According to one recent study, 78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs.[14] Through such conduct, branded manufacturers create serial barriers to hold off the type of competitive entry that is fundamental to our innovative system.

[14] Robin Feldman, *May your drug price be evergreen*, Journal of Law and the Biosciences, at 596-97 (Dec. 7, 2018).

81. Jazz's patents can be grouped into three families: the '431 family, the '730 family, and the '302 family. Because the active pharmaceutical ingredient in Xyrem, sodium oxybate, has long been known, none of the patents in these families claim the active pharmaceutical compound.

1. The '431 Family of Patents (Formulations and Methods of Treatment)

82. The '431 family of patents all claim priority to U.S. Patent Application No. 09/470,570, which Orphan Medical filed on December 22, 1999. Jazz obtained most of these patents more than a decade after obtaining the parent patent. As shown below, Jazz sought and obtained these additional patents as part of an abusive scheme to forestall litigation brought by generic manufacturers. The patents in the '431 family include both the '431 and '889 patents obtained by Orphan, and the following patents listed below as covering Xyrem:

THE '431 PATENT FAMILY:
LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
7,262,219	July 7, 2004	Aug. 28, 2007	July 4, 2020
7,851,506	July 13, 2007	Dec. 14, 2010	Dec. 22, 2019
8,263,650	Apr. 13, 2012	Sept. 11, 2012	Dec. 22, 2019
8,324,275	Apr. 13, 2012	Dec. 4, 2012	Dec. 22, 2019
8,859,619	Nov. 26, 2012	Oct. 14, 2014	Dec. 22, 2019
8,952,062	March 6, 2013	Feb. 10, 2015	Dec. 22, 2019
9,539,330	Nov. 9, 2015	Nov. 8, 2016	Dec. 22, 2019

83. The '431 family of patents includes Orange Book-listed patents that claim pharmaceutical formulations of sodium oxybate or other salts of GHB (the '889, '219, '650, '619, and '330 patents) and/or methods of treating sleep-related conditions with sodium oxybate or other salts of GHB (the '506, '650, '275, and '062 patents).

84. The patents in the ’431 family also include two patents that claim specific processes for manufacturing Xyrem. As process patents, they are not listable in the Orange Book.[15]

85. The patents in the ’431 family were set to expire on December 22, 2019, with the exception of the ’889 and ’219 patents, which received patent term adjustments under 35 U.S.C. § 154(b). In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents, and that six-month exclusivity expired June 22, 2020 (for the ’506,’650, ’275, ’619, ’062 and ’330 patents) and January 4, 2021 (for the ’889 and ’219 patents). The process patents have expired.

2. The ’730 Family of Patents (Drug Distribution System and Method)

86. The ’730 family of patents all claim priority to U.S. Patent Application No. 10/322,348, which Orphan Medical filed on December 17, 2002. The ’730 family of patents are titled “Sensitive Drug Distribution System and Method.”

87. The patents in the ’730 family include the following patents that Jazz and/or Orphan Medical requested be listed in the Orange Book as covering Xyrem:[16]

[15] These patents are: Patent No. 6,472,421, issued Oct. 22, 2002 and expired Dec. 22, 2019, and Patent No. 8,461,203, issued June 11, 2013 and expired Dec. 22, 2019.

[16] The ’730 family also includes United States Patent No. 7,797,171, which issued on September 14, 2010. The ’171 patent claims methods of obtaining FDA approval for a prescription drug that uses a controlled distribution method involving an exclusive central computer database. Jazz did not list the ’171 patent in the Orange Book and has not asserted this patent against any ANDA applicant for generic Xyrem.

THE ’730 PATENT FAMILY:
LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
7,668,730	Dec. 17, 2002	Feb. 23, 2010	June 16, 2024
7,765,106	Nov. 2, 2004	July 27, 2010	June 16, 2024
7,765,107	Apr. 1, 2005	July 27, 2010	June 16, 2024
7,895,059	Feb. 11, 2010	Feb. 22, 2011	Dec. 17, 2022
8,457,988	Aug. 27, 2012	June 4, 2013	Dec. 17, 2022
8,589,182	Aug. 27, 2012	Nov. 19, 2013	Dec. 17, 2022
8,732,963	Aug. 22, 2012	May 20, 2014	Dec. 17, 2022

88. The patents in the ’730 family “relat[e] to a drug distribution system for tracking prescriptions of a ‘sensitive drug,’” which is “one which can be abused, or has addiction properties or other properties that render the drug sensitive.”[17]

89. In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents for Xyrem. The expiration of that six-month exclusivity was listed in the Orange Book as December 16, 2024 for the ’730, ’106 and ’107 patents and as June 17, 2023 for the ’059, ’988, ’182, and ’963 patents. As described below, the Patent Trial and Appeal Board (“PTAB”) later found this family of patents to be invalid.

3. The ’302 Family of Patents (Method of Administration)

90. The ’302 family of patents all claim priority to United States Patent Application No. 13/837,714, which Jazz filed on March 15, 2013. The ’302 family of patents are all titled “Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters.”

[17] *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 895 F.3d 1347, 1350 (Fed. Cir. 2018).

91. The patents in the ’302 family include the following patents that Jazz requested be listed in the Orange Book as covering Xyrem:

THE ’302 PATENT FAMILY:
LISTED IN THE ORANGE BOOK

U.S. Patent No.	Application Date	Issue Date	Expiry (without pediatric exclusivity)
9,050,302	Mar. 15, 2013	June 9, 2015	Mar. 15, 2033
8,772,306	Apr. 29, 2013	July 8, 2014	Mar. 15, 2033
9,486,426	May 8, 2015	Nov. 8, 2016	Mar. 15, 2033
10,213,400	Jan. 12, 2018	Feb. 26, 2019	Mar. 15, 2033

92. The patents in the ’302 family claim methods of treating sleeping disorders by decreasing the amount of sodium oxybate or other salt of GHB administered to the patient if the patient is also taking valproate or divalproex sodium, medications used to treat seizures.

93. In 2018, the FDA granted pediatric exclusivity to the Orange Book-listed patents for Xyrem. The expiration of that six-month exclusivity is listed in the Orange Book as September 15, 2033 for the patents in the ’302 family with the exception of the ’400 patent, which did not issue and was not listed in the Orange Book until 2019 and is not currently listed in the Orange Book with pediatric exclusivity.

E. After Flirting with Bankruptcy, in 2009 Jazz Changes Management and Embarks on a Strategy of Large Xyrem Price Increases

94. In 2006, Xyrem revenues were approximately $26 million. Jazz reportedly lost $82 million that year.[18] In June 2007, Jazz went public through an Initial Public Offering (“IPO”). The IPO was considered something of a failure because Jazz raised

[18] Alex Berenson, *Manufacturer of Risky Drug to Sell Shares*, New York Times (May 31, 2007), available at https://tinyurl.com/y4wo8q9t.

$108 million as compared to earlier hopes that it would raise $180 million.[19] Jazz's stock price soon began to fall from its IPO offering of $18/share.

95. By early 2009, Jazz was reportedly on the brink of bankruptcy.[20] Its stock price fell below $1/share. It put its drug development program on hold. It laid off 24% of its workforce. In April 2009, it replaced its CEO with Jazz co-founder Bruce Cozadd.

96. Jazz's new management determined that its path to success was through aggressive Xyrem price increases. According to Jazz's new CFO, Kate Falberg, Jazz increased its first quarter 2010 product sales to $34.3 million, an increase of 61% over the first quarter of 2009, "driven primarily by price increases taken on Xyrem during 2009."[21] Jazz reported that gross margin on all product sales was greater than 90%.

97. Jazz President Bob Myers reported in that call that, effective May 1, 2010, "we've taken a price increase for Xyrem of approximately 15%." Myers added that "it's important to remember that the vast majority of our Xyrem patients have fixed monthly co-pays" and therefore should not see any impact to their monthly co-pay from price increase. Myers also announced that Jazz would, as necessary, provide copay assistance to patients, the effect of which was to ensure that third-party payors, like UHS, would absorb the price increase. While it extracted ever-increasing prices from third-party

[19] David P. Hamilton, *Jazz Pharma takes it on the chin, raises less-than-expected $108M in IPO*, Venture Beat (May 31, 2007), available at https://tinyurl.com/y4oxf9vh.

[20] Jim Edwards, *How a Sleeping Drug Company Increased Prices 300% Without Anyone Noticing*, CBS News (Nov. 12, 2010), available at https://tinyurl.com/y5kgvfgt.

[21] Jazz Pharmaceuticals, Inc. Q1 2010 Earnings Call Transcript (May 5, 2010), available at https://tinyurl.com/yyssjm6s.

payors like UHS, Jazz used the supracompetitive profits it generated to ensure that patients never saw those increases. As Jazz recognized, nearly 90% of its sales were to patients insured under commercial insurance plans; Medicare Part D and Medicaid comprised less than 10% and 4% respectively.[22] Xyrem patients paid on average $50/month and no more than $100/month.[23]

F. Jazz Seeks a Multiple Pharmacy REMS in Conjunction With its Request for Approval to Market Xyrem for Fibromyalgia

98. In August 2009, Jazz submitted a REMS proposal that would, among other things, remove the restriction to a single pharmacy and instead allow certification of multiple pharmacies. Jazz wrote that this proposed change would "increase patient access without compromising patient safety."[24] Jazz stated that the existing single centralized pharmacy program "imposes numerous impediments to patient access to Xyrem, possibly depriving narcolepsy patients of an important medication to control their EDS and cataplexy and potentially affect their lives dramatically."[25]

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[22] *See, e.g.*, UBS Global Life Sciences Conference (Sep. 20, 2011), available at https://tinyurl.com/y2pz92ue. These data are as of 2011, but UHS alleges they are representative of the relevant time period. Of the remaining patient population, Jazz sponsored a Patient Assistance Program to provide Xyrem at no or low cost for uninsured patients with a financial need.

[23] *See, e.g.*, Final Transcript, Jazz Pharmaceuticals Inc. at LCM Annual Healthcare Conference (Nov. 17, 2010), available at https://tinyurl.com/y4lchnrs.

[24] Memorandum from Trueman Sharp to Abbreviated New Drug Applications (ANDAs) for sodium oxybate oral solution products, *et seq.* (Jan. 17, 2017), attached as Exhibit B and incorporated by reference into this Complaint.

[25] Sharp Memorandum, *supra*, n. 24.

99. In December 2009, Jazz submitted an NDA seeking approval for a new indication for fibromyalgia. In that NDA, Jazz proposed a REMS with multiple certified pharmacies.

G. The FDA Rejects Jazz's Fibromyalgia Indication; Roxane (Hikma) Seeks Generic Entry

100. On August 20, 2010, an FDA advisory panel overwhelmingly rejected Jazz's request for a fibromyalgia indication (for reasons entirely unrelated to the multiple certified pharmacies aspect of the proposal).[26] After the FDA declined to approve the fibromyalgia indication, its discussion with Jazz regarding the REMS for Xyrem continued.

101. On July 8, 2010, Roxane submitted ANDA 202090, seeking FDA approval to market an AB-rated generic version of Xyrem in 500 mg/ml strength. Roxane was the first generic to file, making it potentially eligible for 180-day exclusivity when its ANDA got approved. Roxane's ANDA proposed use of its own pharmacy dispensing program to meet Xyrem REMS requirements.

102. Roxane's ANDA included Paragraph IV certifications to the five patents that, at that time, were listed in the Orange Book for Xyrem: the '889 patent and '219 patents from the '431 family, the '730 patent, and the '106 patent and '107 patents.

103. On October 14, 2010, Roxane notified Jazz of its original ANDA filing and provided a detailed account of why the '889, '219, '730, '106 and '107 patents were

[26] Matt McMillen, *FDA Panel Rejects Xyrem as Fibromyalgia Treatment*, WebMD (Aug. 20, 2010), available at https://tinyurl.com/y2k8cc3b.

invalid, unenforceable, and/or not infringed by Roxane's ANDA product ("Paragraph IV notice letter"). Roxane's ANDA presented a grave threat to Jazz because any generic entrant would crush Jazz's core revenue stream.

H. Jazz Initiates an Abusive Litigation Scheme

104. On November 22, 2010, Jazz filed suit against Hikma[27] alleging infringement of the five patents. In early 2011, Jazz commenced two additional lawsuits to add three more patents.

105. Over the course of litigation between Jazz and Hikma, a pattern developed in which (1) Jazz would hold patent applications pending, (2) glean Hikma's noninfringement defenses from the litigation or notice letters, and then, many years after issuance of the parent patents, (3) file continuation applications for new patent claims to delay the litigation and forestall Hikma's noninfringement defenses. Once it obtained the new patents, Jazz would assert them in new infringement claims and lawsuits. Once Hikma responded to the new lawsuits, the cycle would repeat. Through this artifice, Jazz presented a moving target that kept the litigation on a treadmill. This happened ***eight times*** over a five-year period.[28] In one court filing, Hikma wrote that Jazz was engaged

[27] Jazz originally filed suit against Roxane prior to Hikma's acquisition of Roxane. As stated above, references to "Hikma" include Roxane.

[28] Case No. 2:11-cv-00660 (Feb. 4, 2011) alleging infringement of patents '431 and '506; Case No. 2:cv-02523 (May 2, 2011) alleging infringement of '059 patent; Case No. 2:12-cv-06761 (Oct. 26, 2012), alleging infringement of '650 patent; Case No. 2:12-cv-07459 (Dec. 5, 2012), alleging infringement of '275 patent; Case No. 2:15-cv-01360 (Feb. 20, 2015), alleging infringement of '203, '306, and '619 patents; Case No. 2:15-cv-03684 (June 1, 2015), alleging infringement of '062 patent; Case No. 2:16-cv-00469 (Jan. 27, 2016), alleging infringement of '302 patent; Case No. 2:16-cv-04971 (Aug. 12, 2016),

in an "abusive scheme to unfairly multiply this litigation" to "extend the life cycle of its monopoly."[29]

106. For example,

- In response to Jazz's original complaint alleging infringement of the '506 patent, Hikma asserted that it would not infringe the '506 patent because "all of the claims in the '506 patent required that the sodium oxybate solution be administered using a concentrated medium of 500 mg/ml of sodium oxybate" but the "administration of [Hikma]'s sodium oxybate solution required dilution of the concentrated medium prior to patient administration."[30] Hikma disclosed this defense as part of the invalidity and non-infringement contentions it provided to Jazz in April and August 2011.[31] In response—fourteen years after filing the parent patent application and after Hikma relied on the patents to design its generic product—Jazz filed new continuation patents containing claims calling for dilution of the sodium oxybate solution prior to patient administration. These patents ('650 and'275) were issued in September 2012 and December 2012, respectively. Jazz then sued Hikma in October 2012 and December 2012, respectively alleging infringement of the '650 and '275 patents.

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alleging infringement of '963 patent.

[29] Memorandum in Support of Roxane's Motion for Leave to Amend Its Answers, ECF No. 221, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, No. 2:10-cv-06108 (D.N.J. May 3, 2013).

[30] Roxane Laboratories, Inc.'s Amended Answer, Affirmative Defenses and Counterclaims to Plaintiff's Complaint Regarding U.S. Patent No. 8,263,650 ("No. 2:10-cv-06108 Affirmative Defenses") ¶¶ 17-18, ECF No. 218-3, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc*., No. 2:10-cv-06108 (D.N.J. Apr. 26, 2013).

[31] *Id*., No. 2:10-cv-06108 Affirmative Defenses ¶ 14.

- When Hikma contended that it did not infringe the ’219 or ’889 patents because the claims of those patents require the inclusion of “a pH adjusting agent” and Hikma’s product did not contain a pH adjusting agent, Jazz responded by filing an application for the ’650 patent, which included claims to compositions that do not require “a pH adjusting agent.” Once it obtained the patent, Jazz asserted it against Hikma.[32]

- When Hikma contended that it did not infringe the ’431 patent because “[a]ll of the claims of the ’431 patent require that sodium oxybate be ‘added’ to an aqueous medium” and “[Hikma] makes its sodium oxybate solution without ‘adding’ sodium oxybate to an aqueous medium,” Jazz filed the patent application that issued as the ’203 patent. After obtaining that patent in June 2013, Jazz then asserted it against Hikma.[33]

107. As Hikma wrote in the patent litigation, “Jazz continues to seek and obtain new patents, add patents to the Orange Book, bring patent infringement suits against [Hikma], including to seek consolidation of all suits relating to [Hikma]’s sodium oxybate ANDA product.” [34] Hikma argued that Jazz’s abusive conduct would cause it to “continue to suffer material prejudice by being forced to indefinitely defend itself against patents that were not invented by the named inventors but are based on information

[32] No. 2:10-cv-06108 Affirmative Defenses ¶¶ 22-26.

[33] No. 2:10-cv-06108 Affirmative Defenses ¶¶ 27-31.

[34] Roxane Laboratories, Inc.’s Answer, Affirmative Defenses and Counterclaims to Plaintiff’s Complaint (“No. 2:15-cv-01360 Affirmative Defenses”) ¶ 83, ECF No. 12, *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc*., No. 2:15-cv-01360 (D.N.J. Apr. 20, 2015).

gleaned by patent attorneys during a litigation, causing [Hikma] to face an 'at-risk' launch of its sodium oxybate product due to delayed resolution of this litigation."[35]

108. In a November 2010 investor presentation, Jazz's CEO, Bruce Cozadd, boasted that "Some people may not remember this, but shortly before Roxane submitted their ANDA, there were two patents covering Xyrem, we are now up to 10 with additional patents in the pipeline."[36] When asked about the possibility of settling the patent litigation, Cozadd said Jazz had not "ruled it out" but "our job" is to "do what we believe creates the most value for shareholders."[37]

109. To support its assertion that Xyrem would be protected from competition in the future, Jazz displayed the slide below at the November investor conference.[38]

[35] No. 2:15-cv-01360 Affirmative Defenses ¶ 33.

[36] Jazz Pharmaceuticals' CEO Presents at Lazard Capital Markets Healthcare Conference (Transcript) (Nov. 14, 2012), available at https://tinyurl.com/y6so78p2.

[37] *Id.*

[38] UBS Global Life Sciences Conference (Sep. 20, 2011), available at https://tinyurl.com/y2pz92ue. The asterisks denote patents listed in the Orange Book.

Strong Sodium Oxybate Patent Coverage

XYREM (sodium oxybate) oral solution

	Number	Issue Date	Expiration Date
Distribution system patent*	7,765,106	7/27/2010	6/16/2024
Distribution system patent*	7,765,107	7/27/2010	6/16/2024
Distribution system patent	7,797,171	9/14/2010	6/16/2024
Distribution system patent*	7,668,730	2/23/2010	6/16/2024
Distribution system patent*	7,895,059	2/23/2011	12/17/2022
Formulation patent*	6,780,889	8/24/1999	7/4/2020
Formulation patent*	7,262,219	8/28/2007	7/4/2020
Process patent	6,472,431	10/29/1999	12/22/2019
Method of use patent*	7,851,506	12/14/2010	12/22/2019

I. Jazz Continues to Increase Prices Dramatically While It Staves Off Generic Competition Through Unlawful Means

110. In a November 2010 conference call, Myers said Jazz was implementing a 22% price increase for Xyrem. Myers said Jazz could increase by more but wanted to "avoid big jumps in price" to stay below a "price ceiling" so as "to not raise the scrutiny of payors or plans."[39]

111. Jazz CEO Cozadd noted Jazz had "substantial pricing power" because there is "nothing else that does what [Xyrem] does. There is no substitute."[40] By that time, November 2010, Jazz's stock price had grown to more than $50/share—a 5,000% increase over its 2009 low—largely based on Xyrem price increases.

J. Jazz Reverses Course in Its REMS Negotiations and Files Sham Citizen Petitions to Discourage Generic Entry

112. In early 2011, after the FDA rejected Jazz's fibromyalgia indication, Jazz dropped its proposal for certification of multiple pharmacies and proposed—again—a single certified pharmacy. By that time, Jazz had obtained several of its REMS patents ('730 Family) and listed them in the Orange Book.

113. In a November 2011 investor conference, Cozadd was asked to comment on the possibility of generic entry.[41] He responded that the "restricted distribution system

[39] Jim Edwards, *How a Sleeping Drug Company Increased Prices 300% Without Anyone Noticing*, CBS News (Nov. 12, 2010), available at https://tinyurl.com/y5kgvfgt.

[40] Final Transcript, Jazz Pharmaceuticals Inc. at LCM Annual Healthcare Conference (Nov. 17, 2010), available at https://tinyurl.com/y4lchnrs.

[41] Conference Call Transcript, JAZZ – Jazz Pharmaceuticals, Inc. at Piper Jaffray Health Care Conference (Nov. 30, 2011), available at https://tinyurl.com/y5m5rb7n.

patents, we think, are particularly important" and "any generic company—Roxane included—will have a difficult time setting up their own distribution system that" did not infringe Jazz's REMS patents. Asked how Jazz could believe it properly obtained patents for an FDA-approved process, Cozadd responded that the "patents exist, so somebody's going to have to make a compelling argument that that was a mistake."[42]

114. On May 18, 2012, Jazz submitted to the FDA a baseless citizen petition, Docket No. FDA-2012-P-0499, asking the FDA to (i) immediately publish whether generic Xyrem ANDAs were required to prove bioequivalence to the brand using in vitro testing, in vivo testing, or both, (ii) not accept, review, or approve any ANDAs until after this information had been published, and (iii) require *in vivo* bioequivalence testing, including both fed and fasting conditions, "and a demonstration of onset of drug action similar to Xyrem," for any proposed ANDA product that differs from the brand in manufacturing process, pH, excipients, impurities, degradants or contaminants.

115. Jazz attached forty-nine exhibits to its May 2012 citizen petition, including numerous scientific studies spanning many hundreds of pages and, at footnote 2, an implicit threat to sue if the FDA's review and response was not sufficiently thorough: "it would . . . be arbitrary and capricious for the FDA to deny [the requests] without a substantive response."[43]

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[42] *Id.*

[43] Jazz Pharmaceuticals Citizen Petition to FDCA (May 18, 2012), p. 2 n. 2, https://beta.regulations.gov/document/FDA-2012-P-0499-0001.

116. On July 10, 2012, before the FDA had responded to Jazz's May 2012 citizen petition, Jazz submitted to the FDA a second citizen petition concerning the requirements for submission of ANDAs referencing Xyrem, Docket No. FDA-2012-P-0733, and asked the FDA to rescind the acceptance of any previously accepted ANDA (including the ANDA submitted by Hikma) that did not include a proposed risk management system when accepted for FDA review, arguing that such ANDAs would not contain the same labeling and conditions as Xyrem, as required by law.[44]

117. The July 2012 citizen petition further requested that the FDA (i) not accept for review any ANDA referencing Xyrem that did not contain, at the time of its submission, a proposed risk management system sufficient to demonstrate that the new generic drug product has the same labeling and conditions of use as Xyrem; and (ii) determine that if any sponsor, including Hikma, submitted an ANDA referencing Xyrem that did not contain a proposed risk management system at the time it was accepted for review, or later submits or resubmits an ANDA that contains an adequate proposed risk management system, then such ANDA should be subject to a renewed automatic 30-month stay of approval in the event Jazz timely opted to initiate patent litigation based on such notice.

118. In August 2012, the FDA provided interim comments on the proposed REMS that stated the final REMS should ***not*** contain the single pharmacy limitation. The FDA wrote that the restriction to a single pharmacy was not necessary or appropriate

[44] Jazz Pharmaceuticals Citizen Petition to FDCA (July 10, 2012), https://beta.regulations.gov/document/FDA-2012-P-0733-0001.

to ensure the safe use of Xyrem and that any pharmacy that could meet the requirements for certification could safely dispense Xyrem. The FDA added that the single-pharmacy restriction could unduly burden patient access and the health care delivery system.[45]

119. On November 13, 2012, the FDA denied Jazz's May 18, 2012 citizen petition. In its 20-page opinion, the FDA found that, contrary to Jazz's contention, it is not required to publish bioequivalence guidance prior to accepting ANDAs, nor is it required to reject ANDAs submitted prior to such publication. The FDA noted that publication of bioequivalence guidance is intended to benefit ANDA applicants, whereas the only beneficiary of Jazz's baseless interpretation is brand manufacturers like Jazz, "who will benefit from a delay in generic competition in the marketplace."[46]

120. Because the Xyrem "deemed REMS" included ETASU, generic applicants were required to participate with Jazz in a "single shared system" REMS. In October 2012, Roxane first contacted Jazz regarding the development of a single shared system REMS.

121. In December 10, 2012, Amneal submitted an ANDA seeking FDA approval to market an AB-rated generic version of Xyrem. After Amneal sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Amneal.

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[45] Sharp Memo, *supra* n. 24, at 6.

[46] FDA Denial of Jazz Pharmaceuticals Citizen Petition Docket No. FDA-2012-P-0499 (Nov. 13, 2012), https://investor.jazzpharma.com/static-files/cea82a5a-360c-40b2-ab5c-d56b2b3a1611.

122. On December 13, 2012, the FDA denied in its entirety Jazz's July 2012 citizen petition finding, as with Jazz's May 2012 citizen petition, that none of the requests had merit.

K. Jazz Continues to Resist FDA Requests for Multiple Certified Pharmacies as Part of a Strategy to Exclude Generic Competition

123. In a May 2013 investor presentation, Jazz predicted that based on the most recent schedule put forth by the court, a trial against Hikma could commence as early as mid-2014.[47] As set forth below, however, Jazz's obstructive conduct delayed the Hikma trial and other trials that would have paved the way for generic entry.

124. In a September 2013 SEC filing, Jazz noted the importance of its REMS dispute with the FDA and the threat posed by generic entrants. Jazz publicly touted its *seriatim* patent applications and associated lawsuits to assure investors that Jazz would continue to achieve monopoly profits from Xyrem. Jazz wrote that "depending on the extent to which certain provisions of our Xyrem deemed REMS . . . are changed as part of updating our REMS documents, the ability of our existing patents to protect our Xyrem distribution system from generic competitors may be reduced."[48]

125. In a December 2013 investor update, Jazz CEO Bruce Cozadd (purporting to quote from a recent court proceeding) said that "there are 78 claims at stake" and, if

[47] Jazz Pharmaceuticals Public Limited Company Presents at UBS Global Healthcare Conference (May 21, 2013), available at https://tinyurl.com/yy4deld2.

[48] Jazz Pharmaceuticals Form 10-Q, at 54 (Nov. 5, 2013), https://tinyurl.com/y5qc6om5.

Hikma didn't prevail on all 78, it would lose the patent litigation. Cozadd added: "So we think the breadth of our IP protection for the product is very important."[49]

126. On November 20, 2013, Par Pharmaceutical, Inc. filed an ANDA seeking to market its AB-rated generic version of Xyrem. After Par sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Par.

127. In December 2013, in an effort to bring the protracted discussions over the Xyrem REMS to a close, the FDA informed Jazz that the Agency was requiring a modification to the REMS under the FDA's statutory authority which, among other things, would have removed the single pharmacy restriction. The FDA also sent a draft template for the REMS to at least one of the ANDA applicants to facilitate the development of a single shared system REMS.

128. At the same time that it was resisting the FDA's efforts to modify the Xyrem REMS to allow for multiple pharmacies, Jazz was obstructing ANDA applicants who were seeking to meet their obligation to participate in a singled shared system REMS. According to filings with the FDA, numerous ANDA applicants accused Jazz of engaging in a strategy that "entails serial attempts to impose unreasonable contractual

[49] Transcript of Jazz Pharmaceuticals' CEO Presents at 25th Annual Piper Jaffray Healthcare Conference (Dec. 3, 2013), https://tinyurl.com/y4gmllfy. Notably, Cozadd's compensation was largely tied to Jazz's stock price. In 2013, Cozadd reportedly earned more than $8 million in annual compensation from Jazz, largely from Jazz stock (which, in turn, was artificially inflated by Jazz's unlawful conduct). Cozadd thus had a strong personal financial incentive to artificially extend the Xyrem monopoly.

terms and conditions on the ANDA [filers] while concurrently issuing self-serving statements to FDA and the ANDA [filers] about Jazz's commitment to the process."[50]

129. In January 2014, the FDA hosted a meeting between Jazz and an unidentified ANDA applicant to facilitate development of a shared REMS. The ANDA applicant proposed a timeline with 30, 60, and 90-day deliverables, offered to provide a confidentiality and non-disclosure agreement, and otherwise sought to facilitate a smooth REMS development protocol. The ANDA applicant provided the non-disclosure agreement in January 2014, but Jazz stretched out negotiations for the next seven months.

130. In March 2014, when the unidentified ANDA applicant learned of Jazz's dispute resolution request with the FDA, the applicant expressed concern about delays. The FDA directed the parties to continue working together to develop a shared REMS.

131. In February 2014, Jazz filed a formal dispute resolution request to appeal the FDA's notification, arguing that the FDA "lacked statutory authority to modify a REMS 'deemed' to be in effect by operation of FDAAA, and alternatively, even if FDA did have such authority, it could only be exercised to add restrictions to a REMS, not to modify or remove elements."[51]

132. In May 2014, the FDA denied Jazz's dispute resolution request. Jazz appealed that decision to the Director of the Office of New Drugs in June 2014. At an August 2014 meeting to discuss the ongoing dispute, a Jazz representative acknowledged

[50] Sharp Memorandum, *supra*, n. 24 at 11.

[51] Sharp Memorandum, *supra*, n. 24 at 7.

that a multiple pharmacy distribution system could effectively prevent the abuse, misuse, and diversion of sodium oxybate, but continued to seek a single pharmacy REMS. The FDA repeated its twin goals, to have a REMS that assures safe use of the drug and "to ensure that the REMS does not stand in the way of generic approval."[52]

133. On June 3, 2014, Ranbaxy Laboratories, Ltd. filed an ANDA seeking approval to market an AB-rated generic version of Xyrem. After Ranbaxy sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Ranbaxy.

134. On October 29, 2014, Watson Laboratories, Inc. filed an ANDA seeking approval to market an AB-rated generic version of Xyrem. After Watson sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Watson.

L. The FDA Reluctantly Relents and Approves Jazz's Single-Pharmacy REMS

135. In February 2015, the FDA chose "to close a chapter" on the Jazz REMS application.[53] The FDA noted the "repeated, lengthy delays" caused by Jazz had resulted in the REMS application pending "far longer than could have reasonably been anticipated."[54] The FDA wrote that it would accept Jazz's proposed REMS, not because it believed the REMS to be the best path forward, but to put an end to the "significant drain on Agency resources posed by the dispute, and the fact that the outcome of Jazz's

[52] Sharp Memorandum, *supra* n. 24, at 7.

[53] Letter from Billy Dunn, MD, to Jazz Pharmaceuticals, attached as Exhibit C and incorporated by reference into this Complaint.

[54] Sharp Memorandum, *supra* n. 24, at 3.

challenge to the Agency's legal authority to require a modification to a 'deemed REMS' had the potential to affect only a small number of drug products."[55]

136. The FDA made clear its disapproval of Jazz's anticompetitive acts. The FDA noted Jazz's "inconsistent" positions over the course of the approval process, and quoted Jazz's 2013 SEC statement regarding the adverse effect that a multiple REMS system could have on Jazz's ability to protect its distribution system from generic competitors. Taken together, the FDA wrote, these facts suggested "Jazz's awareness" that it could use REMS to block or delay generic versions of Xyrem in a manner inconsistent with the FDCA.

137. To add an extra measure of clarity, the FDA wrote that its action "should not be construed or understood as agreement with Jazz that limiting dispensing to a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh the risks." Instead, the FDA wrote, "We continue to be concerned that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system. No other currently approved REMS requires a sponsor to limit dispensing to a single pharmacy." [56]

138. On June 8, 2015, Wockhardt Bio AG filed an ANDA seeking approval to market an AB-rated generic version of Xyrem. After Wockhardt sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Wockhardt.

[55] Sharp Memorandum, *supra*, n. 24.

[56] Sharp Memorandum, *supra*, n. 24 at 7.

139. On July 23, 2015, Lupin Ltd. and Lupin Pharmaceuticals Inc. filed an ANDA seeking approval to market an AB-rated generic version of Xyrem. After Lupin sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Lupin.

M. After FDA Approval of Its REMS, Jazz Continues to Use REMS to Block Generic Entry

140. In August 2015, an ANDA applicant emailed the FDA to report a lack of progress in efforts to participate in a single shared system REMS. The FDA hosted a teleconference among the parties in October 2015.

141. In December 2015, Jazz submitted a letter to the FDA opposing a potential waiver of the shared system requirement, arguing the FDA could not grant a waiver and approve a separate REMS that utilizes multiple pharmacies. The FDA rejected Jazz's arguments. The FDA hosted another teleconference in March 2016, but the parties were no further along than before.

142. In April 2016, the ANDA applicant submitted a REMS amendment proposing a joint separate REMS system for generic Xyrem. Additional ANDA applicants similarly sought waivers.

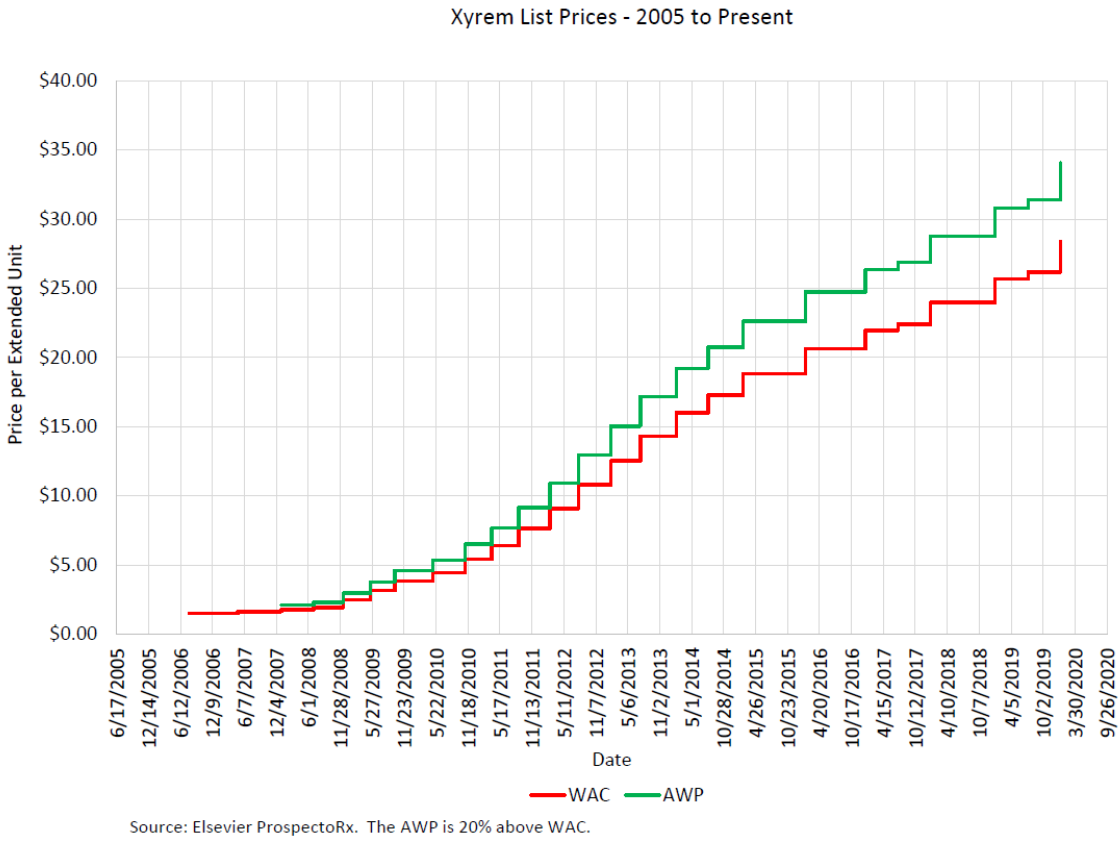
143. In January 2017, the FDA granted a waiver of the REMS requirement for multiple ANDA applicants. In ruling, the FDA restated its concern that Jazz was improperly manipulating the system to discourage generic entry. The FDA found that the burdens on the health care system were outweighed by the benefits and that the burdens on patients of multiple REMS were minimal. The FDA wrote that it "has been waiting to

approve any sodium oxybate ANDAs pending development of" a shared system REMS. It further noted the "obvious incentives" for Jazz to "delay generic competition, including by failing to agree" on a shared system REMS. The FDA held that by granting a waiver, it was removing a "barrier to generic products coming to market."

N. Jazz's Unlawful Conduct Enabled It to Increase Prices Dramatically

144. When Jazz first acquired Orphan Medical, a one-year supply of Xyrem cost about $5,000 to $10,000. Prior to the change in Jazz management, Xyrem prices increased at a moderate pace. As shown in the chart below, Jazz's new management began to increase prices at a dramatic pace beginning in 2009. Seven years later, a one-year supply cost about $62,000 to $124,000.[57] Price increases continued at the same breakneck pace through at least 2020.

[57] The recommended dose of Xyrem ranges from 4.5 to 9 grams, which converts to a monthly dosage range of 270 to 540 mL. So, in 2007, the yearly cost of Xyrem ranged from $6,609.60 to $13,219.20. But by 2014, the yearly cost for the drug had ballooned to a range from $62,208 to $124,416.



145. In May of 2014, Bloomberg published a ranking of drug price increases from 2007 to 2014. Xyrem ranked first with an overall increase of 841% from 2007 to 2014. According to Bloomberg, Jazz increased prices by 51%, 49%, 41%, 41%, 41%, 32%, and 12% annually from 2007-14.

146. The pricing history of Xyrem stands in contrast to that of other branded drugs. From 2009 to 2018, Xyrem's WAC price increased 525%, as compared to an average of just over 100% for all other brand drugs for which data are available.

147. Jazz's ability to increase price was attributed to several factors. First, Xyrem did not face any generic competition. Second, there were no therapeutic substitutes for Xyrem. During the relevant time period, other medications were available to treat narcolepsy, but none provide the same clinical outcomes with the same side

effects. Third, most patients were insured and therefore were insulated from cost increases. As Cozadd explained in a 2010 earnings call, "the vast majority" of patients have fixed monthly co-pays.[58] As a result, third-party payors like UHS absorbed the cost of price increases. Jazz sponsored programs to help insureds obtain payment from third-party payors.

148. Due to its monopoly position, Jazz was not incentivized to offer or negotiate meaningful rebates to third-party payors, including UHS.

149. Jazz's price increases were pure profit. Gross margins on the sale of Xyrem were well over 90%.

150. In 2007, Jazz reported net sales of $39 million for Xyrem, which made up about three-quarters of the company's net sales of all products for the year. In 2019, Jazz reported total revenue from Xyrem of about $1.6 billion, which again accounted for about three-quarters of the company's net product sales. In 2019, Jazz realized gross margins in excess of 95 percent.

O. The Patents in the '730 Family Are Declared Invalid

151. Beginning in January 2015, would-be generics for Xyrem filed a series of petitions with the PTAB for *inter partes* review ("IPR") of the '730 family of patents relating to the distribution system for sensitive drugs. Claims in all of the '730 family of patents were challenged in the proceedings and, eventually, found to be invalid.

[58] Jazz Pharmaceuticals, Inc. Q1 2010 Earnings Call Transcript (May 5, 2010), https://seekingalpha.com/article/203249-jazz-pharmaceuticals-inc-q1-2010-earnings-call-transcript.

152. Collectively, and as consolidated, Par and Amneal challenged claims in the '730, '106, '107, '059, '988, '182, and '936 patents. Each of the challenged patents derives from the same original application filed in 2002 by Orphan Medical, and each contains, as noted above, claims relating to a drug distribution system and method that utilizes a central pharmacy and database to track prescription.

153. On April 28, 2016, Jazz settled with Wockhardt (one of the generics that was pressing IPR review), resolving not only the IPR proceedings, but also the patent infringement litigation Jazz had filed against Wockhardt. That settlement agreement, according to Jazz's public filings, granted Wockhardt a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or ostensibly "earlier" depending on the occurrence of certain events. The specific terms of the settlement agreements are confidential. Jazz and Wockhardt then sought, and were granted, termination of the IPR proceedings as to Wockhardt.

154. Days later, on May 9, 2016, Jazz settled with Ranbaxy. Jazz gave Ranbaxy a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or ostensibly "earlier" depending on the occurrence of "certain events." That settlement also is confidential. With its settlement, Ranbaxy's IPRs and civil counterclaims in the Hatch-Waxman litigation pending against it were terminated.

155. From July 2016 to March 2017, with just Amneal and Par remaining as petitioners, the PTAB issued a series of six decisions finding that "by a preponderance of the evidence" all claims of the '730, '106, '107, '059, '182, '988 patents, and claims 24, 26, and 27 of the '963 patent, were unpatentable as obvious.

156. The PTAB found that these claims, which related to Jazz's REMS program and described a centralized database containing patient, physician, and prescription information, were obvious because Orphan Medical had disclosed the program long before it filed the first patent application (i.e., Orphan's disclosure at a publicly-held FDA Advisory Committee meeting on June 6, 2001) and such information was posted to the FDA's website.

157. Jazz appealed the ruling to the Federal Circuit. In July 2018, the Federal Circuit affirmed the PTAB invalidity rulings.

P. Hikma Obtains Final ANDA Approval for Generic Xyrem

158. On January 17, 2017, with its infringement trial with Jazz just six months away, Hikma obtained final approval from the FDA for its generic Xyrem ANDA.

159. In its approval of Hikma's ANDA, the FDA also issued a decision to waive the requirements for a single, shared system REMS for Xyrem, meaning that Hikma was no longer required under FDA regulations to seek a license to rely on Jazz's Xyrem REMS protocol. The decision referenced the ANDAs of Hikma and Amneal, among other applicants whose names were redacted, and provided that they or any other generic sodium oxybate oral solution manufacturer could also rely on Hikma's REMS program (and not be required to use Jazz's).

160. In issuing its decision, the FDA reiterated the ANDA filers' allegations that Jazz ha[d] engaged in a strategy that "entails serial attempts to impose unreasonable contractual terms and conditions on the ANDA [filers] while concurrently issuing self-serving statements to FDA and the ANDA [filers] about Jazz's commitment to the

process."[59] This "strategy" of obstructive negotiation by Jazz of the single, shared program went on for more than three years. Ultimately, the FDA determined that "[i]n the absence of a waiver of the SSS [single, shared system] requirement, the ANDA [redacted] and Jazz's failure to agree to SSS terms is likely to further delay the approval of a generic version of sodium oxybate," and accordingly waived the single, shared requirement for Xyrem.[60]

Q. The Jazz-Hikma Reverse Payment Agreement

161. By the spring of 2017, Hikma had received final FDA approval for its generic product, and no statutory exclusivities stood in the way of its market entry. Hikma's trial challenging Jazz's remaining Xyrem patents was set to begin in only a few weeks. Under its approved application, there was no legal obstruction to Hikma entering the U.S. market with its own approved product, its own pharmacy arrangements, and its own approved REMS program.

162. Such a full market entry by Hikma would likely have caused Jazz to immediately launch its own authorized generic. By that time, Jazz had already reached agreements with at least five other ANDA filers, each of which obtained a license to enter with their generic product on or after December 31, 2025, or earlier depending on the occurrence of "certain events." Taken together, if Hikma entered the market, other

[59] See FDA Memorandum, Decision to waive the requirement for a single, shared system REMS for sodium oxybate oral solution, January 17, 2017, at 11, available at https://tinyurl.com/yyhp3dct.

[60] *Id*. at 12-13.

generic manufacturers would have launched six months after Hikma exhausted its 180 days of first-filer exclusivity.

163. On April 5, 2017 Jazz and Hikma entered into a "settlement agreement" under which Hikma agreed to drop its patent challenge on the terms, and for the consideration, summarized below. This agreement not only kept Hikma out of the market for sodium oxybate, but—because Hikma was the first-filed ANDA applicant—it also effectively blocked (and continues to block) other generic entrants.

164. The April 2017 Jazz-Hikma agreement was, in part, memorialized in three documents, a "Settlement Agreement," a "License Agreement," and an "AG Agreement," which the parties executed contemporaneously. The "Settlement Agreement" between Jazz and Hikma was partially disclosed in a Form 8-K. Jazz and Hikma agreed not to disclose the other two documents. All the written and tacit arrangements between Jazz and Hikma in April of 2017 were negotiated simultaneously, are interdependent, and are collectively referred to in this complaint as the "Jazz-Hikma Agreement."

165. Under the Jazz-Hikma Agreement, Jazz granted Hikma (via its subsidiary, West-Ward Pharmaceuticals) the right to sell an authorized generic version of Xyrem in the U.S. for an initial term of six months commencing on January 1, 2023 "or earlier under certain circumstances." Those circumstances include market entry of another generic version of Xyrem, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time. Jazz also gave Hikma the right to extend the initial six-month

term to sell an authorized generic version of Xyrem for up to a total of five years (January 1, 2028).

166. In return, Hikma agreed to pay Jazz "a meaningful royalty" on net sales of the AG, with the royalty rate increasing based on increased net sales of the authorized generic. There will be a "substantial increase in the royalty rate" if Hikma's AG sales extend beyond one year.

167. Hikma agreed to purchase its supply from Jazz and distribute the AG through the Jazz REMS. Hikma agreed to pay Jazz for supply of the AG in an amount that was not disclosed and "reimburse[]" Jazz for a portion of the services costs associated with the operation of the Xyrem REMS and distribution of the AG.

168. Jazz also granted Hikma a non-exclusive license under the Xyrem patents to make, have made, and market its generic sodium oxybate product under the Roxane ANDA in the U.S., which license was to be effective after the end of the AG sales period. Hikma agreed that it would not otherwise make, use, or sell a generic version of Xyrem for "so long as the Xyrem Patents remain in effect."

169. Hikma has a license to launch its generic product as of July 1, 2023, but if it chooses to do so, Hikma will no longer have the right to sell an AG product through the Xyrem REMS.

170. Finally, under the agreement, Jazz agreed to pay Hikma an undisclosed sum of money ostensibly in "recognition of the savings inuring to Jazz in terms of the avoidance of costs and expenditure of time and resources" prosecuting the litigation against Hikma.

171. As described above, the Jazz-Hikma Agreement contained payments from Jazz to Hikma in the forms of cash and a "no-AG" agreement whereby Jazz promised not to launch its own AG product in competition with Hikma. At the time they settled, Jazz and Hikma were well aware that antitrust law forbade reverse-payment agreements and sought to create the false appearance of a permissible arrangement.

R. The Jazz-Hikma Agreement Has Caused, and Will Continue to Cause, Anticompetitive Effects

172. The Jazz-Hikma Agreement has caused, and will continue to cause, numerous anticompetitive effects. But for the Agreement, Hikma would have pursued its meritorious patent challenge, which would have paved the way for Hikma's generic entry by as early as January 2018, and additional generic entrants after expiration of Hikma's 180-day exclusivity period. As shown above, and for the reasons asserted in the Jazz-Hikma patent case, Jazz's patents were unenforceable and, even if they may have been enforceable against other ANDA applicants, Jazz's generic product would not have infringed Jazz's patents. Hikma's entry into the market for sodium oxybate would have created price competition and exhausted Hikma's first-filer rights, thus paving the way for the line of additional ANDA applicants. The harm caused by this aspect of the Jazz-Hikma agreement is continuing, and will continue until expiration of the agreement absent judicial intervention.

173. In the alternative to pursuing its patent challenge to a conclusion in the courts, but for the reverse-payment terms of the Agreement, Jazz and Hikma would have

settled on terms that did not include reverse payments and other anticompetitive provisions, thus paving the way for unrestricted generic entry long before July 2023.

174. While the Agreement technically permits Hikma to launch its own FDA-approved generic before July 2023, the Agreement creates a situation in which it would be economically illogical for Hikma to do so. By selling its own FDA-approved generic Hikma would forfeit its Hikma AG rights and its access to Jazz's REMS. Jazz would launch its own AG, thus creating price competition that would reduce Hikma's profits. It would trigger the rights of other would-be generic competitors to enter the market without restriction after expiration of the 180-day exclusivity period, thus reducing potential profits substantially.

175. Although not explicitly set forth in the Jazz-Hikma Settlement Agreement, Jazz at least tacitly agreed not to launch its own AG if Hikma sold an authorized AG pursuant to the Agreement. Indeed, the Agreement was structured so that Jazz shared in the supracompetitive profits that Hikma would obtain through sales of its authorized generic. The Agreement required Hikma to purchase the product from Jazz, to make royalty payments to Jazz, and "reimburse" Jazz for distribution costs. These provisions eliminated any rational economic incentive for Jazz to compete against Hikma in the market for sodium oxybate.

176. Under the terms of the Jazz-Hikma Agreement, sales of Hikma's AG would follow the same route as Xyrem, via the ESSDS pharmacy. In fact, it does not appear that Hikma would ever take delivery of its AG product.

177. The Jazz-Hikma Agreement's "acceleration clause" discouraged generic entry by creating a situation in which any generic that sought to compete on the merits would be met with robust competition from Hikma and Jazz (through its own AG). This clause set the stage for subsequent reverse-payment agreements with generic manufacturers who could not claim first-to-file status.

178. The provision in the Jazz-Hikma Agreement requiring Hikma to pay an escalating royalty based on the level of net sales of Hikma's AG discourages Hikma from competing on price without restriction. If Hikma lowers price to increase sales volumes, it would pay to Jazz any profit that it would otherwise obtain from increased market share.

179. Prior to discovery, UHS must rely on publicly available evidence to preliminarily estimate the dollar value of the reverse payment to Hikma by measuring the difference between the profits that Hikma would have earned had it launched in January 2018 ("but-for profits") against the profits it can reasonably expect to earn via the reverse-payment agreement.

180. To estimate Hikma's but-for profits, one can apply certain well-grounded assumptions to publicly known facts. First, to estimate what Hikma would likely have earned had it entered the market in 2018, one can start from the fact that Jazz reported approximately $1.5 billion in annual Xyrem sales. Based on empirical data on generic entry, one can reasonably assume that (a) the generic products (including an authorized generic) would have captured 80% of Xyrem sales by discounting generic prices by as much as 50% off the brand price and (b) Hikma would have captured half of all generic

Xyrem sales. This implies that Hikma's generic product would have generated sales of $150 million during a six-month exclusivity period beginning in January 2018. This does not account for the increased costs that Hikma would have had to pay to distribute its generic product through its separate REMS.

181. Second, to predict what Hikma will actually earn in generic sales in 2023, one can reasonably anticipate that Jazz will continue to aggressively implement price increases on its branded products. If one conservatively assumes 8% annual increases, that implies sales of at least $2.2 billion. Hikma will capture all generic sales—which would be approximately 80% of branded sales. And, because it will not have to compete against a Jazz AG, Hikma can price its generic product at a smaller discount (20%) to the branded price. Applying these assumptions, Hikma will earn $705 million during its period of exclusivity. The value to Hikma of the reverse payment agreement is therefore in excess of $550 million (again, excluding saved costs from use of Jazz's REMS). The variable "royalties" in the Jazz-Hikma agreement have the purpose and effect of maintaining higher prices by creating disincentives to capture volume at the expense of Xyrem.

182. There are unknown and complicating factors by both the varying "royalties" and the intended longevity of the lucrative Hikma AG that forestalls bona fide generic entry. But as a matter of sound applied microeconomics, in all events Hikma receives a payment markedly larger than it could receive if it had entered the market under competitive conditions.

183. This calculation only accounts for the revenues to Hikma during the first six months after launch. The agreement permits Hikma's AG sales to be extended for up to five years. It is fair to add to the parameters for measuring the size of the payment to Hikma that the size will increase due to the likely longer term of the Hikma AG.

S. The Jazz-Hikma Agreement Harmed Competition and Purchasers

184. The Jazz-Hikma Agreement delayed unrestrained generic competition which would have inured to the benefit of purchasers. As discussed, a reverse-payment agreement provides substantial profit to the brand manufacturer due to the elimination of price competition and continuation of the brand's monopoly and shares a portion of those profits (more than the generic would have made had it competed on the merits for market share) with the generic. While this arrangement is profitable for drug makers, the supracompetitive profits are all extracted from purchasers. In particular, in the specific context of Xyrem, the supracompetitive profits are extracted from third-party payors, including UHS.

185. The reaction of Jazz's stock price to news of the Jazz-Hikma Agreement confirms its anticompetitive effect. On April 6, the day following the announcement of the Jazz-Hikma Agreement, Jazz's stock rose from $140.65 at the close of markets on April 5, to $153.88 per share at the close on April 6. This change may represent an increase in Jazz's value of approximately $785 million, depending on the effects of other events that day that might have affected Jazz's value or that of the market as a whole. One can credibly attribute this increase in stock price to the changed expectations of

investors who, prior to the news, expected generic competition to erode Jazz's Xyrem profits.

T. Two More Generic Manufacturers Seek Entry

186. On June 14, 2017, Ascent Pharmaceuticals, Inc. submitted an ANDA seeking FDA approval to market an AB-rated generic version of Xyrem. After Ascent sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Ascent.

187. On November 21, 2017, Mallinckrodt plc, Mallinckrodt Inc., and Mallinckrodt LLC submitted an ANDA seeking FDA approval to market an AB-rated generic version of Xyrem. After Mallinckrodt sent its initial Paragraph IV notice letter to Jazz, Jazz filed a patent infringement action against Mallinckrodt.

U. Jazz Enters into Unlawful Reverse Payment Agreements with Par, Lupin, and Amneal

188. By 2018, Jazz had effectively forestalled generic entry for sodium oxybate oral solution. But while Hikma (the first-to-file ANDA applicant) and several other generics had abandoned their challenges to the Xyrem patents, other generic companies continued to press forward. If these later challengers succeeded, they would pave the way for generic entry by numerous companies, including Hikma and the other settlers (per the acceleration clauses in those agreements).

189. Over the course of 2018, Jazz entered into a series of additional anticompetitive reverse payment settlements.

1. The Jazz-Par Reverse Payment Agreement

190. In January 2018, Jazz and generic maker Par entered into a reverse payment agreement (the "Jazz-Par Agreement"). Under that Agreement, Jazz granted Par a right to sell a limited volume of an authorized generic version of Xyrem (the "Par AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of AG that Par was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume during the calendar year preceding the entry date of the Par AG. In effect, Jazz simply agreed to pay to Par a share of the supracompetitive profits it was gaining through the anticompetitive conditions it had created.

191. In exchange for this share of Jazz's brand Xyrem revenue (via volume-limited AG supply), Par agreed to abandon its challenge to Jazz's patents and delay launch of its own, true generic until December 31, 2025. The Jazz-Par Agreement also included an "acceleration clause" that allows earlier entry if the Jazz patents were invalidated, another generic manufacturer entered the market, or there is a substantial reduction in Xyrem net sales over a specified period of time.

192. By entering into the Jazz-Par Agreement, Par knowingly became a part of the overall arrangements to allocate the market for sodium oxybate.

193. The reverse payment from Jazz to Par is objectively valued in at least the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of Jazz's saved litigation costs.

2. The Jazz-Lupin Reverse Payment Agreement

194. In June 2018, Jazz and generic maker Lupin entered into a reverse payment agreement (the "Jazz-Lupin Agreement").

195. Under the Jazz-Lupin Agreement, Jazz granted Lupin a right to sell a limited volume of an authorized generic version of Xyrem (the "Lupin AG") for a term beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of the Lupin AG that Lupin was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume.

196. The Jazz- Lupin Agreement also included an "acceleration clause" that allows earlier entry if the Jazz patents were invalidated, another generic manufacturer entered the market, or there is a substantial reduction in Xyrem net sales over a specified period of time.

197. By entering into the Jazz- Lupin Agreement, Lupin knowingly became a part of the overall arrangements to allocate the market for sodium oxybate.

198. The reverse payment from Jazz to Lupin is objectively valued in at least the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

3. The Jazz-Amneal Reverse Payment Agreement

199. In October 2018, Jazz and generic maker Amneal entered into an anticompetitive reverse payment agreement (the "Jazz-Amneal Agreement").

200. Under the Jazz-Amneal Agreement, Jazz granted Amneal a right to sell a limited volume of an authorized generic version of Xyrem (the "Amneal AG") for a term

beginning July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. The volume of the Amneal AG that Amneal was permitted to sell was limited to "a low single digit percentage" of Xyrem sales volume.

201. At the time of entering into the Jazz-Amneal Agreement, Amneal was aware of the arrangements between Jazz, Hikma, Lupin, and Amneal.

202. By entering into the Jazz-Amneal Agreement, Amneal knowingly agreed to the overall arrangements to allocate the market for sodium oxybate.

203. The Jazz-Amneal Agreement also included an "acceleration clause" that allows earlier entry if the Jazz patents were invalidated, another generic manufacturer entered the market, or there is a substantial reduction in Xyrem net sales over a specified period of time.

204. By entering into the Jazz-Amneal Agreement, Amneal knowingly became a part of the overall arrangements to allocate the market for sodium oxybate.

205. The reverse payment from Jazz to Par is objectively valued in at least the tens of millions of dollars and constitutes a large and unexplained payment exceeding any reasonable estimate of saved litigation costs.

206. Although the precise percentage of the brand Xyrem market allocated to Jazz's would-be generic competitors under each of Jazz's agreements with Par, Lupin, and Amneal is not publicly known, the value of these allocations can be generally approximated by observing that every one percent of brand sales allocated in 2023 represents a value of approximately $19.8 million per year, assuming $2.2 billion annual

brand sales in the year preceding their entry and a discount of 10% off of brand pricing ($2.2 billion x 0.01 x 0.90 = $19.8 million).

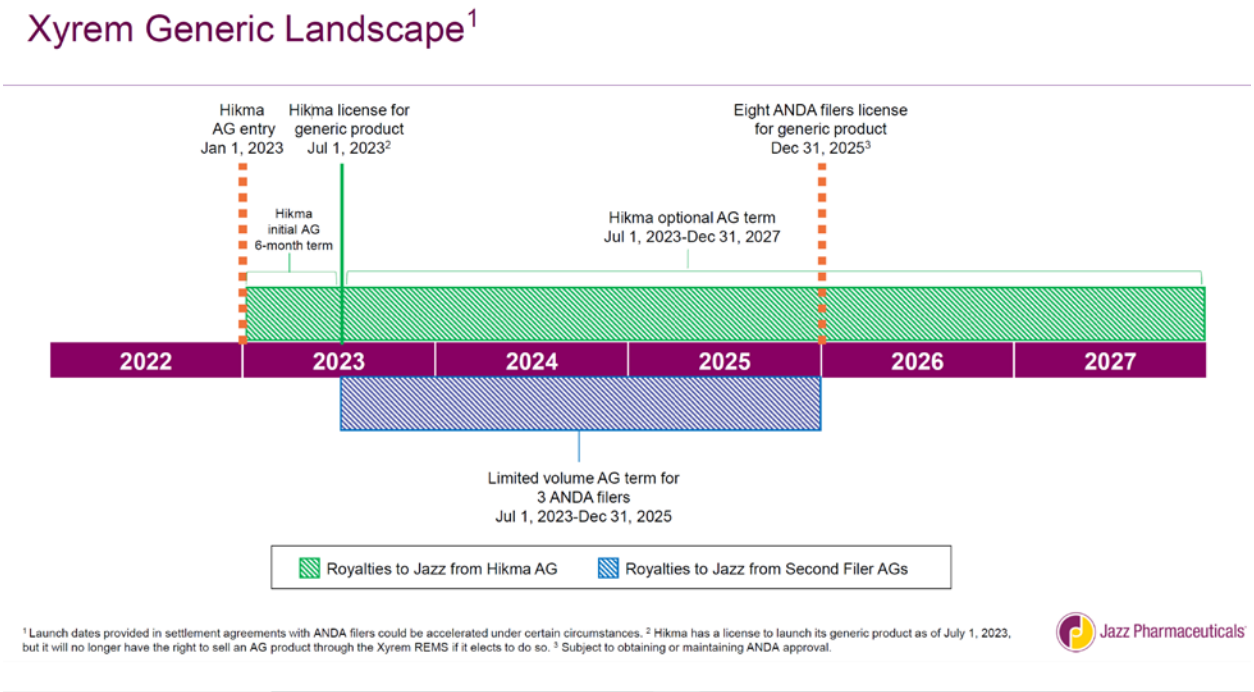
207. As with the Jazz-Hikma Agreement, Jazz's agreements with Par, Lupin, and Amneal will not increase overall output, reduce price, or increase consumer choice; they will merely substitute Par, Lupin, and Amneal as the sellers of millions of dollars' worth of Xyrem for the sole purpose of paying them to delay market entry of less-expensive generic sodium oxybate, preserving Jazz's massive monopoly profits in exchange for doling out a small slice of them to Par, Lupin, and Amneal.

208. In December 2019, Jazz CEO Bruce Cozadd was asked about the impact of generic competition after Hikma and others enter the market. Cozadd responded that "in terms of dynamics on price, it's – this is not what you would think of as a generic free for all" because of the "very limited volumes" for Par, Lupin, and Amneal.[61]

209. During a healthcare conference call on November 14, 2018, a senior Jazz executive explained that the Jazz-Hikma Agreement would provide Jazz with "meaningful royalties and would provide Hikma with meaningful economics during that first year." After that first year, "the royalties become even more meaningful for Jazz." Then, after expiration of Hikma's six-month exclusivity period, the second filers are limited to such low sales volumes that there will be a "relatively low incursion on Xyrem." Then, at the end of 2025, all eight second filers will have an opportunity to bring a generic product to the market. The graphic below, taken from a Jazz presentation,

[61] Jazz Pharmaceuticals plc Conference Presentation (Dec. 4, 2019).

depicts the "generic landscape." The profits to Jazz, Hikma, and the other settlers are, and will be, taken at the expense of UHS and other third-party payors.



210. Jazz launched Xywav in November 2020. Xywav is a therapeutic equivalent of Xyrem. Jazz has indicated its intention to price Xywav at, or even below, Xyrem, to encourage third-party payors to shift coverage to Xywav. If a lower-priced generic sodium oxybate product were available, third-party payors (including UHS) could potentially exclude both Xyrem and Xywav from their commercial insurance plans in favor of the lower-priced generic sodium oxybate product.

V. Since Its Launch in 2002, Jazz Has Dispensed Xyrem Through, and Coordinated Pricing With, ESSDS

211. Jazz has at all times dispensed Xyrem to consumers exclusively through ESSDS pursuant to the single centralized pharmacy REMS. ESSDS agreed to "not

provide any of the Services provided pursuant to this Agreement to any third party with respect to a pharmaceutical product containing sodium oxybate."

212. Under Jazz's and ESSDS's master services agreement, Xyrem is dispensed as "delineated in written work orders from Jazz." ESSDS ships Xyrem directly to each patient or patient-authorized adult designee. ESSDS tracks and verifies receipt of each Xyrem shipment.

213. The Master Services Agreement ("MSA") between Jazz and ESSDS identifies two categories of sales methods.[62] In the first, ESSDS holds Xyrem in a secure facility on a "consignment" basis and then dispenses Xyrem to the patient. In these sales, ESSDS does not take title to the Xyrem. In the second, title for the Xyrem product passes from Jazz to ESSDS momentarily upon the point of "removal" from the ESSDS Central Certified Pharmacy. The second category only applies to sales made as part of a "buy in" option. Because complete underlying documents are not publicly available, UHS does not have the specifics of the "buy-in" category.

214. The full terms of the agreement between Jazz and ESSDS are not publicly known. According to a redacted version of the MSA, Jazz exerts control over the prices that ESSDS charges for Xyrem sales. The MSA imposes a limit (price "shall not exceed" the "greater of [redacted] percent of [redacted]"). The MSA states that the price at which ESSDS can sell Xyrem is adjusted by percentage (which is not disclosed) of a particular benchmark price over a period of years. On information and belief, Jazz and ESSDS

[62] Pharmacy Master Services Agreement (July 17, 2017), available at https://tinyurl.com/y5uqsod6.

coordinate pricing of Xyrem sold to UHS and other purchasers. Jazz ultimately controlled the price at which ESDDS charged UHS and third-party payors.

215. Jazz pays ESSDS a fee for its service as the approved REMS pharmacy.

216. For the reasons described above, ESSDS is more like a subsidiary or an affiliate of Jazz than an independent purchaser. On information and belief, ESSDS also encouraged and/or aided Jazz's efforts to restrict distribution of Xyrem to a single certified pharmacy.

W. Defendants Intended To, and Did, Harm Competition in the Market for Sodium Oxybate

217. Jazz's conduct as described above harmed competition in at least several respects. First, by, insisting on a single certified distributor, Jazz prevented downstream competition on price among competing distributors.

218. Second, Jazz intended to, and did in fact, block and delay generic manufacturers from entering the market, disrupted the normal distribution channels, and manipulated the statutory and regulatory mechanisms by which generic competition takes place.

219. Third, Jazz unjustifiably refused to cooperate with the generic ANDA filers to prevent them from obtaining FDA approval.

220. Fourth, Jazz's abuse of the REMS process, its sham litigation and objectively unsustainable patents, and frivolous citizens' petitions delayed generic competition to Xyrem.

221. Fifth, the pay-for-delay agreements blocked and delayed generic entry.

222. As shown above, generic entrants typically price their products at a discount to the then-prevailing price for the branded product. The first generic entrant generally prices at a modest discount to the branded price. When more than one generic manufacturer enters the market, generic prices fall rapidly, and those generic products capture most of the branded's sales volumes. This is known as the generic "cliff." That is what would have happened with Xyrem were a generic allowed to enter the market. Had Jazz and the generics manufacturer defendants not entered into anticompetitive agreements, the first generic entrant would have discounted from a lower price point and competition would have rapidly driven prices down to competitive levels, as early as January 2018, and certainly earlier than 2023.

223. Jazz cannot justify its scheme by pointing to any offsetting procompetitive or consumer benefit. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Jazz could possibly offer.

X. Jazz's Monopoly Power

224. Jazz has monopoly power in the market for sodium oxybate because it has 100% market share and possesses the power to exclude competition and/or raise or maintain the price of branded sodium oxybate at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. In a November 2011 investor call, Jazz's CEO said of Xyrem, "There's really no competition. The other drugs used to treat narcolepsy for the excessive daytime sleepiness part of narcolepsy are stimulants. Those can and are used together with Xyrem, so that's not an either/or, it's an and

proposition. Probably 80% to 90% of our patients and the patients in our clinical trials were also on stimulants."[63]

225. Jazz's monopoly power is demonstrated by its ability to significantly increase Xyrem prices without losing enough sales to make the price increases unprofitable. Other treatments for cataplexy and EDS associated with narcolepsy are not therapeutic substitutes because those products are not therapeutically equivalent. Physicians typically prescribed Xyrem *in addition to* other treatments for narcolepsy, such as amphetamines or wakefulness drugs. The fact that Xyrem is not a therapeutic substitute for those other products is demonstrated by the fact that lower-priced generic versions of those products were available during the conduct period, but those lower-priced generic drugs did not take market share from Xyrem.

226. Branded Xyrem does not exhibit significant, positive cross-elasticity of demand with respect to price with any other pharmaceutical product or treatment for cataplexy or EDS associated with narcolepsy other than AB-rated generic versions of Xyrem. That is, in the absence of AB-rated generics, a small but significant and non-transitory increase in the price of Xyrem would not, and did not, cause Jazz to lose sufficient sales to other drugs to make the price increase unprofitable.

227. Jazz needs to control only sodium oxybate products in order to maintain the price of its branded sodium oxybate products profitably at supracompetitive prices. Only the market entry of competing, AB-rated generic versions would prevent Jazz from

[63] Conference Call Transcript, *supra*, n. 2.

maintaining extremely high and profitable prices for branded sodium oxybate products without losing substantial sales.

228. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Xyrem (and will protect Xywav) from the forces of unrestrained price competition.

229. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Jazz's ability to control the price of sodium oxybate, and/or to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (a) generic sodium oxybate would have entered the market at a much earlier date, at a substantial discount to branded Xyrem, but for Defendants' anticompetitive conduct; (b) Jazz's gross margin on Xyrem (including the costs of ongoing research/development and marketing) at all relevant times was very high—in excess of 90%; and (c) Jazz never lowered the price of Xyrem to the competitive level in response to the pricing of other brand or generic drugs.

230. To the extent that UHS is required to prove monopoly power circumstantially by first defining the relevant product market, UHS alleges a relevant product market for antitrust purposes that consists of sodium oxybate (Xyrem, Xywav, and its AB-rated generic equivalents). The relevant geographic market is the United States including, but not limited to, Minnesota.

Y. Effects on Interstate and Minnesota Trade and Commerce

231. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

232. At all material times, Xyrem, manufactured and sold by Jazz, was shipped across state lines and sold to customers outside its state of manufacture. Jazz directed the sale of Xyrem throughout the United States and into Minnesota.

233. Defendants' unlawful activities, as described in this Complaint, affected both intrastate commerce in Minnesota and interstate commerce flowing into or out from Minnesota.

234. At all relevant times, UHS, a Minnesota corporation headquartered in Minnesota, was contractually responsible for the payments for the drugs at issue dispensed to UnitedHealthcare Insureds. UHS entered agreements with PBMs, pursuant to which UHS was, and is, responsible for paying for pharmaceutical drugs, including Xyrem, prescribed and dispensed to UnitedHealthcare Insureds throughout the United States. UHS entered these contracts, received invoices, and ensured and administered payment pursuant thereto in amounts totaling millions of dollars for the drugs at issue at its headquarters in Hennepin County, Minnesota. Employees involved with making, processing, and managing payments to the PBMs for UnitedHealthcare Insured's claims for the drugs at issue work and reside in Minnesota. Likewise, employees with knowledge of UHS's agreements and payment relationships work and reside in Minnesota.

235. The anticompetitive acts by Defendants and their co-conspirators had, and continue to have, a direct, substantial, and reasonably foreseeable effect on Minnesota trade and commerce, including by artificially raising and fixing prices for the drugs at issue, as were paid in, and/or out from, Minnesota, and otherwise injuring corporations and persons located in Minnesota.

Z. Antitrust Injury

236. During the relevant period, UHS paid for substantial quantities of Xyrem at supracompetitive prices. As a result of Defendants' illegal conduct, UHS paid and is still paying artificially inflated prices for sodium oxybate, due to the lack of a generic sodium oxybate product. The prices UHS paid, and will in the future pay for Xyrem and/or Xywav, were and are substantially greater than the prices that would have been paid absent the illegal conduct alleged in this Complaint, because: (1) the price of Xyrem (and Xywav) was artificially inflated by Defendants' illegal conduct, and (2) UHS was and still is deprived of the opportunity to pay for lower-priced generic sodium oxybate.

237. As a direct and proximate result of Defendants' conduct, UHS sustained substantial losses and damages to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial. UHS alleges that the anticompetitive effects of the conduct are still ongoing.

238. The impact of Defendants' conduct on the price of Xyrem and Xywav is measurable and quantifiable. Commonly used and well-accepted economic models can be used to measure both the existence and the amount of the supracompetitive charges paid by UHS. Thus, the economic harm alleged can be quantified.

AA. UHS' Claims are Timely

239. A cause of action accrued to UHS each time it paid an overcharge—*i.e.*, each time it made a payment for Xyrem at a price higher than would have been paid absent Defendants' unlawful conduct. UHS alleges that it began to pay overcharges as early as 2018.

240. UHS reserves its right to allege that it began to pay overcharges at an earlier time based on evidence disclosed in discovery. As noted above, much of the unlawful conduct occurred in legal proceedings governed by confidentiality orders that limited public disclosure of the underlying facts. For example, the facts alleged in the Jazz-Hikma patent proceedings were largely protected from public disclosure. Similarly, the Jazz-Hikma Agreement has not been fully disclosed, nor has the MSA between Jazz and ESSDS.

VI. CLAIMS FOR RELIEF

COUNT 1 – VIOLATION OF 15 U.S.C. § 1
(Against Jazz and Hikma)

241. UHS hereby repeats and incorporates by reference each preceding paragraph.

242. Jazz and Hikma violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for sodium oxybate.

243. UHS has been injured in its business or property by the violation of 15 U.S.C. § 1. UHS's injury consists of having paid and continuing to pay higher prices for

its sodium oxybate requirements than it would have paid in the absence of those violations.

244. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

245. As a direct and proximate result of Jazz and Hikma's anticompetitive conduct, UHS was harmed and continues to be harmed.

COUNT 2 – VIOLATION OF 15 U.S.C. § 1
(Against Jazz and Amneal)

246. UHS hereby repeats and incorporates by reference each preceding paragraph.

247. Jazz and Amneal violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for sodium oxybate.

248. UHS has been injured in its business or property by the violation of 15 U.S.C. § 1. UHS's injury consists of having paid and continuing to pay higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations.

249. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

250. As a direct and proximate result of Jazz and Amneal's anticompetitive conduct, UHS was harmed and continues to be harmed.

COUNT 3 – VIOLATION OF 15 U.S.C. § 1
(Against Jazz and Lupin)

251. UHS hereby repeats and incorporates by reference each preceding paragraph.

252. Jazz and Lupin violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for sodium oxybate.

253. UHS has been injured in its business or property by the violation of 15 U.S.C. § 1. UHS's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations.

254. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

255. As a direct and proximate result of Jazz and Lupin's anticompetitive conduct, UHS was harmed and continues to be harmed.

COUNT 4 – VIOLATION OF 15 U.S.C. § 1
(Against Jazz and Par)

256. UHS hereby repeats and incorporates by reference each preceding paragraph.

257. Jazz and Par violated 15 U.S.C. § 1 by entering into an unlawful reverse payment agreement that restrained competition in the market for sodium oxybate.

258. UHS has been injured in its business or property by the violation of 15 U.S.C. § 1. UHS's injury consists of having paid higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations.

259. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

260. As a direct and proximate result of Jazz and Par's anticompetitive conduct, UHS was harmed and continues to be harmed.

COUNT 5 – VIOLATION OF 15 U.S.C. § 1
(Against All Defendants)

261. UHS hereby repeats and incorporates by reference each preceding paragraph.

262. The Defendants violated 15 U.S.C. § 1 by entering into an overarching agreement to restrain competition in the market for sodium oxybate.

263. Defendants' agreements were horizontal market allocation and price-fixing agreements between actual or potential competitors and thus are *per se* violations of the Sherman Act.

264. In the alternative, the reverse payment agreements were unreasonable restraints of trade when viewed under a rule of reason analysis because the agreements were not reasonably necessary to accomplish any procompetitive objective and any potential justification would be outweighed by its anticompetitive effects.

265. UHS has been injured in its business or property by the violation of 15 U.S.C. § 1. UHS's injury consists of having paid and continuing to pay higher prices for its sodium oxybate requirements than it would have paid in the absence of those violations.

266. From the launch of the brand Xyrem in 2002 through the present, Jazz possessed, and continues to possess, monopoly power in the relevant market—i.e., the market for sales of sodium oxybate in the United States. But for the Defendants' wrongful conduct, as alleged in this Complaint, Jazz would have lost its monopoly power in the relevant market at least as early as January 1, 2018 and in any event well before 2023.

267. As a direct and proximate result of the Defendants' overarching agreement, UHS was harmed and continues to be harmed.

COUNT 6 – VIOLATION OF 15 USC § 2
(Against Jazz)

268. UHS hereby repeats and incorporates by reference each preceding paragraph.

269. At all relevant times, Jazz possessed monopoly power in the market for sodium oxybate.

270. Jazz knowingly and intentionally maintained and enhanced its monopoly power in the relevant market, as described in this Complaint, injuring UHS. Jazz accomplished this scheme by, *inter alia*, (a) Delaying generic entry of sodium oxybate in order to lengthen the period in which Jazz's branded sodium oxybate products could

monopolize the market and make supra-competitive profits; (b) Keeping an authorized generic off the market during Hikma's 180-day generic exclusivity period, and, subsequently when Amneal, Lupin, and Par are permitted to enter with only limited quantities of generic sodium oxybate, through at least December 31, 2025, thereby allowing Defendants to monopolize the generic market for sodium oxybate during the period, and allowing Defendants to make supracompetitive profits; (c) Raising and maintaining the prices so that UHS would pay supracompetitive prices for branded sodium oxybate; and (d) Otherwise conspiring to unlawfully monopolize the relevant market, including through the use of anticompetitive "acceleration" clauses.

271. The goal, purpose, and effect of Jazz's scheme was also to maintain and extend its monopoly power. Jazz's illegal scheme allowed it to continue charging supracompetitive prices for sodium oxybate, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Jazz's scheme will allow Hikma to reap the benefits of reduced generic competition in the United States. Jazz's conduct was designed to delay the introduction of generic formulations of sodium oxybate into the market and was in violation of Section 2 of the Sherman Act.

272. Because of this unlawful maintenance of monopoly power, UHS paid artificially inflated prices for sodium oxybate.

273. UHS seeks treble damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, for all overcharges proximately caused by the antitrust violation(s) alleged above. Such damages have been suffered in an amount to be proven at trial.

COUNT 7 – VIOLATION OF MINNESOTA ANTITRUST LAW
(Unlawful Monopolization/Conspiracy to Monopolize Against All Defendants – Damages/Monetary Relief for Indirect Purchases/Payments)

274. UHS hereby repeats and incorporates by reference each preceding paragraph.

275. As described above, before January 2023, Jazz will maintain its monopoly power in the relevant market and, after that point, will share its monopoly power with Hikma first, followed by Amneal, Lupin, and Par, in an illegal monopoly.

276. Jazz willfully and unlawfully engaged in continuing illegal conduct to monopolize the relevant market through at least December 31, 2025 by engaging in an anticompetitive scheme to keep AB-rated generic equivalents of Xyrem from the market—not as a result of providing a superior product, business acumen, or historical accident.

277. Jazz knowingly and intentionally maintained and enhanced its monopoly power in the relevant market, as described in this Complaint, injuring UHS. Jazz accomplished this scheme by, *inter alia*, (a) Delaying generic entry of sodium oxybate in order to lengthen the period in which Jazz's branded sodium oxybate products could monopolize the market and make supra-competitive profits; (b) Keeping an authorized generic off the market during Hikma's 180-day generic exclusivity period, and, subsequently when Amneal, Lupin, and Par are permitted to enter with only limited quantities of generic sodium oxybate, through at least December 31, 2025, thereby allowing Defendants to monopolize the generic market for sodium oxybate during the period, and allowing Defendants to make supracompetitive profits; (c) Raising and

maintaining the prices so that UHS would pay supracompetitive prices for branded sodium oxybate; and (d) Otherwise conspiring to unlawfully monopolize the relevant market, including through the use of anticompetitive "acceleration" clauses.

278. The goal, purpose, and effect of Jazz's scheme was also to maintain and extend its monopoly power. Jazz's illegal scheme allowed it to continue charging supracompetitive prices for sodium oxybate, without a substantial loss of sales, reaping substantial unlawful monopoly profits. Jazz's scheme will allow Hikma to reap the benefits of reduced generic competition in Minnesota.

279. There is and was no legitimate, non-pretextual, procompetitive justification for Jazz's conduct that outweighs its harmful effects. Even if there were some conceivable justification, the conduct is and was broader than necessary to achieve such a purpose.

280. As a result of Jazz's illegal conduct, UHS paid, and will continue to pay, artificially inflated prices for sodium oxybate.

281. Had manufacturers of generic sodium oxybate entered the market and lawfully competed with Jazz (and each another) in a timely fashion, UHS would have paid less for sodium oxybate.

282. But for Jazz's illegal conduct, competitors would have begun marketing generic versions of sodium oxybate well before January 2023, and they would be able to market such versions more successfully.

283. By engaging in the foregoing conduct, Jazz intentionally, willfully, and wrongfully monopolized the relevant market in violation of Minnesota law.

284. During the relevant period, many millions of dollars' worth of Xyrem have been, and continue to be, sold and/or paid for in Minnesota each year.

285. The anticompetitive acts by Defendants exerted a substantial and foreseeable effect on Minnesota commerce by artificially fixing and raising prices for Xyrem through their anticompetitive agreements as the prices for Xyrem were paid in, and/or out from, Minnesota.

286. As a proximate result of Defendants' violation of Minnesota antitrust law, UHS has been harmed by paying artificially inflated, supra-competitive prices for sodium oxybate dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

287. UHS seeks treble damages under Minnesota law for all overcharges incurred and paid by UHS as a result of Defendants' conduct, as well as attorneys' fees and costs, and all other forms of relief available pursuant to Minn. Stat. § 325D.49, *et. seq.*

COUNT 8 – VIOLATION OF MINNESOTA ANTITRUST LAW
(Conspiracy in Restraint of Trade Against All Defendants –
Damages/Monetary Relief for Indirect Purchases/Payments)

288. UHS hereby repeats and incorporates by reference each preceding paragraph.

289. Throughout the relevant period, and continuing to the present, Defendants have been and are engaged in a continuing contract, combination or conspiracy with respect to the sale of sodium oxybate in unreasonable restraint of trade and commerce, in violation of Minnesota antitrust law.

290. During the relevant period, Defendants entered into various unlawful reverse payment agreements, as described above, that restrained, and continue to restrain, competition in the market for sodium oxybate.

291. Defendants' acts and combinations in furtherance of the conspiracy have caused unreasonable restraints in the market for sodium oxybate.

292. Defendants' agreements were horizontal market allocation and price-fixing agreements between actual or potential competitors and thus are a *per se* violation of the Minnesota Antitrust Law.

293. In the alternative, the reverse payment agreements were unreasonable restraints of trade when viewed under a rule of reason analysis because the agreements were not reasonably necessary to accomplish any procompetitive objective and any potential justification would be outweighed by their anticompetitive effects.

294. During the relevant period, many millions of dollars' worth of Xyrem have been, and continue to be, sold and/or paid for in Minnesota each year.

295. The anticompetitive acts by Defendants exerted a substantial and foreseeable effect on Minnesota commerce by artificially fixing and raising prices for Xyrem through their anticompetitive agreements as the prices for Xyrem were paid in, and/or out from, Minnesota.

296. As a proximate result of Defendants' violation of Minnesota antitrust law, UHS has been harmed by paying artificially inflated, supra-competitive prices for sodium oxybate dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

297. UHS seeks treble damages under Minnesota law for all overcharges incurred and paid by UHS as a result of Defendants' conduct, as well as attorneys' fees and costs, and all other forms of relief available pursuant to Minn. Stat. § 325D.49, *et. seq.*

COUNT 9 – VIOLATION OF VARIOUS STATE ANTITRUST AND CONSUMER PROTECTION LAWS
(Damages/Monetary Relief for All Indirect Purchases/Payments, In the Alternative)

298. The plaintiff hereby repeats and incorporates by reference each preceding paragraph.

299. This claim for relief is pleaded in the alternative to the Seventh and Eighth Claims for Relief, in the event that the Court disagrees that all of UHS's state law statutory claims for monopolization damages and/or monetary relief for all payments for drugs dispensed to UnitedHealthcare Insureds (to the extent made indirectly) are governed by Minnesota law.

300. UHS asserts that, by engaging in the monopolization conduct alleged above, Jazz has alternatively violated the antitrust and competition statutes of all states and territories that may provide any relief for indirect purchasers/payors, including but not limited to each of the following such laws (provided here as exemplars):[64]

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*,

[64] UHS reserves all rights to assert any and all other state laws that may provide any relief to indirect purchasers/payors (whether conferred by antitrust, unfair deceptive trade practices, consumer protection statutes, or the like).

b. Cal. Bus. & Prof. Code §§ 16600, *et seq.*, Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and the California common law,

c. D.C. Code §§ 28-4503, *et seq.*,

d. Fla. Stat. §§ 501.201, *et seq.*,

e. Hawaii Code §§ 480, *et seq.*,

f. 740 Ill. Comp. Stat. 10/3, *et seq.*,

g. Iowa Code §§ 553.5, *et seq.*,

h. Mass. Gen. L. Ch. 93A, *et seq.*,

i. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*,

j. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*,

k. Minn. Stat. §§ 325D.52, *et seq.*,

l. Miss. Code Ann. §§ 75-21-3, *et seq.*,

m. Neb. Code Ann. §§ 59-802, *et seq.*,

n. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*,

o. N.H. Rev. Stat. Ann. §§ 356.1, *et seq.*,

p. N.M. Stat. Ann. §§ 57-1-2, *et seq.*,

q. N.C. Gen. Stat. §§ 75-2.1, *et seq.*,

r. N.D. Cent. Code §§ 51-08.1-03, *et seq.*,

s. Or. Rev. Stat. §§ 646.705, *et seq.*,

t. 10 L.P.R.A. §§ 257, *et seq.*,

u. R.I. Gen. Laws §§ 6-36-1, *et seq.*,

v. S.D. Codified Laws §§ 37-1-3.2, *et seq.*,

w. Utah Code Ann. §§ 76-10-911, *et seq.*,

x. Vt. Stat. Ann. 9, §§ 2453, *et seq.*,

y. W.Va. Code §§ 47-18-4, *et seq.*, and

z. Wis. Stat. §§ 133.03, *et seq*.

301. In addition, Jazz's conduct further constitutes unfair competition or unfair, unlawful, unconscionable, deceptive, and/or fraudulent acts or practices in violation of the consumer protection statutes, including but not limited to each of the following States and territories:

a. Ark. Code §§ 4-88-101, *et seq.*,

b. Ariz. Code §§ 44-1522, *et seq.*,

c. Cal. Bus. & Prof. Code §§ 17200, *et seq.*,

d. Colo. Rev. Stat §§ 6-1-105, *et seq.*,

e. D.C. Code §§ 28-3901, *et seq.*,

f. Fla. Stat. §§ 501.201, *et seq.*,

g. Idaho Code §§ 48-601, *et seq.*,

h. 815 ILCS §§ 505/1, *et seq.*,

i. Ind. Code §§ 24-5-0.5-1, *et seq.*,

j. Kan. Stat. §§ 50-623, *et seq.*,

k. La. Rev. Stat. Ann. §§ 51:1401, *et seq.*,

l. 5 Me. Rev. Stat. §§ 207, *et seq.*,

m. Mass. Ann. Laws ch. 93A, *et seq.*,

n. Mich. Stat. §§ 445.901, *et seq.*,

o. Minn. Stat. §§ 325D.43, *et. seq*., Minn. Stat. §§ 325F.69, *et seq*., and Minn. Stat. §§ 8.31, *et seq*.,

p. Miss. Code. Ann. §§ 75-24-1, *et seq*.,

q. Missouri Stat. §§ 407.010, *et seq*.,

r. Neb. Rev. Stat. §§ 59-1601, *et seq*.,

s. Nev. Rev. Stat. §§ 598.0903, *et seq*.,

t. N.H. Rev. Stat. §§ 358-A:1, *et seq*.,

u. N.M. Stat. §§ 57-12-1, *et seq*.,

v. N.Y. Gen. Bus. Law §§ 349, *et seq*.,

w. N.C. Gen. Stat. §§ 75-1.1, *et seq*.,

x. N.D. Cent. Code §§ 51-15-01, *et seq*.,

y. Or. Rev. Stat. §§ 646.605, *et seq*.,

z. 73 Pa. Stat. Ann. §§ 201-1, *et seq*.,

aa. S.C. Stat. Ann. §§ 39-5-10, *et seq*.,

bb. S.D. Code Laws §§ 37-24-1, *et seq*.,

cc. Utah Code §§ 13-11-1, *et seq*.,

dd. 9 Vt. §§ 2451, *et seq*.,

ee. Va. Code Ann. §§ 59.1-196, *et seq*.,

ff. W.Va. Code §§ 46A-6-101, *et seq*.,

gg. Wis. Stat. § 100.18; Wis. Stat. §§ 100.20, *et. seq*., and

hh. Wyo. Stat. Ann. §§ 40-12-101, *et seq*.

302. The unlawful acts by Jazz had, and continue to have, a substantial and foreseeable effect on the commerce of each above State and territory by artificially raising and fixing prices for each of the drugs at issue paid for, and/or dispensed in each State or territory.

303. Jazz's unlawful activities, as described in this Complaint, affected both intrastate commerce and interstate commerce flowing into or out from each of the above States and territories, and had direct, substantial and reasonably foreseeable effects upon trade and commerce in each respective State or territory.

304. During the relevant period, through either Jazz itself or the regional and national distributors and retailers that it has engaged for the sale of the drugs at issue, many millions of dollars' worth of those drugs have been, and continue to be, sold in each of the above States and territories every year.

305. As a direct and proximate result of Jazz's violation of each of the foregoing laws, UHS has been harmed by being forced to pay artificially inflated, supra-competitive prices for the drugs dispensed to insureds throughout the United States, and UHS has suffered damages in an amount to be proven at trial.

306. There was and is a gross and unconscionable disparity between the price that UHS paid and continues to pay for the drugs at issue, and the value received, given that more cheaply priced drugs should have been available, and would have been available, absent Jazz's illegal conduct.

307. UHS has been injured and will continue to be injured in its business and property by paying more for the drugs at issue than in the absence of Jazz's unlawful conduct and violation of the foregoing laws.

308. Jazz's conduct in violation of each of the foregoing laws was done knowingly, willfully, and flagrantly.

309. In light of the foregoing, and other facts to be learned and developed through discovery and/or proved at trial, UHS seeks damages, trebled or multiplied to the full extent permitted by each of the foregoing States and territories, for all overcharges incurred and paid by UHS as a result of Jazz's conduct, restitution, as well as attorneys' fees and costs, and all other forms of relief available.

COUNT 10 – UNJUST ENRICHMENT
(Against All Defendants)

310. UHS hereby repeats and incorporates by reference each preceding paragraph.

311. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

312. Defendants have reaped and retained substantially higher profits due to their unlawful scheme.

313. UHS has conferred and continues to confer an economic benefit upon Defendants in the form of profits resulting from the unlawful overcharges from Xyrem sales described in this Complaint, to the economic detriment of UHS.

314. Defendants' financial gain from their unlawful conduct is traceable to overpayments for Xyrem by UHS.

315. UHS has no adequate remedy at law.

316. It would be futile for UHS to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased Xyrem, as those intermediaries are not liable and would not compensate UHS for the Defendants' unlawful conduct.

317. Defendants have benefited from their unlawful acts and it would be inequitable for Defendants to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by Plaintiff.

318. The financial benefits Defendants derived from overcharging UHS for Xyrem is a direct and proximate result of the Defendants' unlawful practices described in this Complaint.

319. The financial benefits Defendants derived are ill-gotten gains that rightfully belong to UHS, who paid and continues to pay artificially inflated prices that inured to Defendants' benefit.

320. It would be wrong and inequitable, under unjust enrichment principles of Minnesota, or alternatively, all States and territories in the United States except Ohio and Indiana, for Defendants to be permitted to retain any of the overcharges that UHS paid for Xyrem that were derived from Defendants' unlawful practices described in this Complaint.

321. Defendants are aware of and appreciate the benefits that UHS has bestowed upon them.

322. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of UHS.

323. UHS seeks the amount of Defendants' ill-gotten gains resulting from their unlawful, unjust, and inequitable conduct, and to the establishment of a constructive trust consisting of such amount.

COUNT 11 – FOR INJUNCTIVE RELIEF FOR VIOLATIONS OF 15 U.S.C. §§ 1, 2 (Against All Defendants)

324. UHS hereby repeats and incorporates by reference each preceding paragraph.

325. As set forth above, Defendants have violated Sections 1 and 2 of the Sherman Act.

326. UHS requests that the Court grant injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26 as may be necessary and appropriate to restore competition in the market for Xyrem. Such relief may include, among other things, an order voiding the reverse-payment agreements identified above.

VII. DEMAND FOR JUDGMENT

327. WHEREFORE, UHS prays for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged in this Complaint is in violation of the law, including each of the laws asserted in this Complaint;

B. An award of UHS's overcharge damages, in an amount to be proven and determined at trial, trebled as provided by law; with pre- and post-judgment interest at the statutory rates;

C. An award to UHS of equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

D. An award to UHS of its reasonable costs and expenses, including attorneys' fees; and

E. An award of all other legal or equitable relief as the Court deems just and proper.

VIII. JURY DEMAND

328. UHS demands a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38(b).

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